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This report provides a review of several of the methods developed by EPA and other Federal and State agencies for assessing ecological impacts or risks associated with the release of toxic or hazardous substances into the environment. Included is a review of legislative or executive directives under which ecological assessment methods have been developed. Three general objectives of ecological assessments are identified and discussed: establishing priorities, developing standards or guidelines and estimating ecological risks to assist management decisions. Qualitative and quantitative methods are discussed, and "top-down" and "bottom-up" approaches are compared. Individual reviews of twenty ecological assessment methods focus on four major components of ecological risk assessment: receptor characterization, hazard assessment, exposure assessment, and risk characterization.

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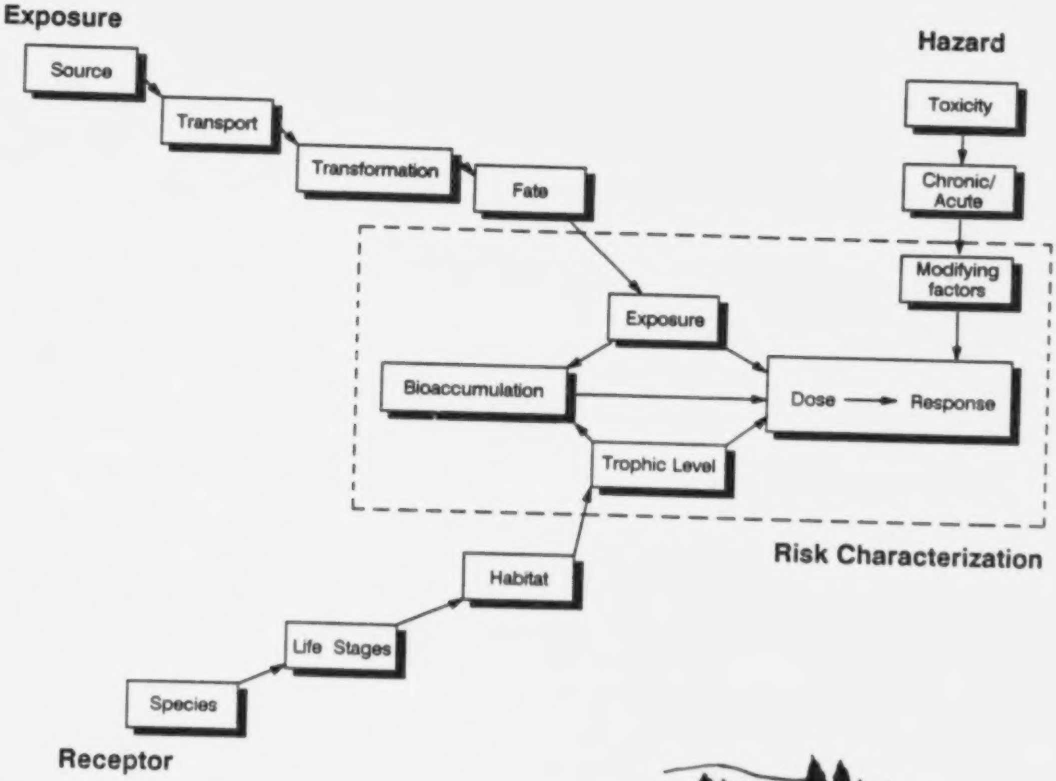
Exposure
Source
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Modifying factors
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Response
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Risk Characterization
Habitat
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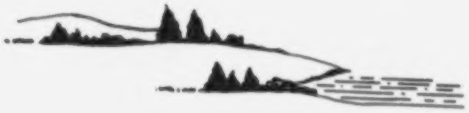

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REVIEW OF ECOLOGICAL RISK ASSESSMENT METHODS

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REVIEW OF ECOLOGICAL RISK ASSESSMENT METHODS

EXECUTIVE SUMMARY

This document reviews several existing methods for conducting ecological assessments to support regulatory decision-making. Ecological risk assessment, strictly defined, is a procedure that predicts the probability of adverse effects to ecosystems, or parts of ecosystems, from environmental pollution. However, the term is often used to encompass many types of ecological assessment procedures being used by EPA to support regulatory decision-making. The methods covered in our review include those that meet the strict definition of ecological risk assessment, as well other types of methods used by state and Federal agencies. Overall, ecological assessment methods reviewed in this document have been developed for three major purposes: priority-setting, developing standards or guidelines, and as input to risk management decisions. These methods are in a constant state of flux, as existing methods are refined, new methods are developed, and the data base needed to support the methods continues to grow.

The purpose of this document is to identify general trends and limitations of ecological assessment as it is currently practiced. We reviewed 20 ecological assessment methods that have been used or are ready to be implemented, and that we consider representative of ecological assessment methods developed by EPA and other Federal and state agencies. We have focused on methods designed to predict the likelihood and magnitude of adverse effects that can result from releases of toxic or hazardous substances into the environment, although several techniques for the assessment of ecological damage are also included. Each method was reviewed using a framework that we developed to ensure consistency among the reviews. The framework consists of a set of characterization points in each of the four major components of the ecological risk assessment process: receptor characterization, hazard assessment, exposure assessment, and risk characterization. We also reviewed the legislative mandates under which the methods were developed, as well as the resources (data, cost, level of expertise) needed to implement the methods.

Most of the methods included in our review are quantitative in nature, although several were qualitative. The qualitative approaches can be used to evaluate problems for which little quantitative information is available, and can be effective for setting priorities, either as ranking or screening procedures. They are generally less resource-intensive than quantitative methods. Nevertheless, qualitative approaches are generally not suitable for developing standards or managing risks; for these applications, a quantitative approach is superior.

The quantitative methods included in our review can be categorized into quotient methods (those that provide a "yes/no" estimate of risk) and continuous methods (those that provide an exposure-dependent estimate of risk). Quotient methods are generally easily implemented, rely on readily available data, and are well-suited for priority-setting and developing standards. Risk management decisions generally require the more complex and realistic continuous methods that provide an exposure-dependent probabilistic estimate of risk. The continuous methods can be used for priority- and standard-setting as well. The most significant drawback to the use of continuous methods is that exposure-response data are not available for many pollutant/receptor combinations.

We found that the ecological assessment methods vary substantially with respect to the receptors and endpoints evaluated. Most of the methods address risks to populations rather than to communities or ecosystems, and the endpoint of concern is often death, although reduced growth and reproduction are also considered. This is primarily because data are often insufficient to support risk assessment at the community and ecosystem levels. For example, exposure-response data using community-level endpoints such as species diversity are extremely limited. Exposure-response data on population-level responses can be used to predict effects at higher levels (i.e., a "bottom up" approach), but there is considerable uncertainty associated with these types of predictions.

There are also differences among the methods in terms of their treatment of uncertainty. Methods that rely on professional judgment do not explicitly address uncertainty. A common way to treat uncertainty is through the use of safety or assessment factors based on data adequacy; this approach is often applied in methods used to set priorities or to develop standards. Most of the risk assessment methods that incorporate exposure-response information attempt to address uncertainty in both the exposure and risk estimates. The techniques used include statistical confidence limits, Monte Carlo simulations, sensitivity analysis, and field validation and calibration.

We found that there are many trade-offs inherent to the ecological assessment process. For example, the more realistic the method, the less likely it is that adequate exposure-response data are available, and the more difficult it becomes to propagate sources of uncertainty throughout the analysis. Currently, the most realistic models used for probabilistic risk assessment require inputs for biological parameters for which few supportive data exist. Although the more complex analyses may more closely approximate real-life conditions, their application may be limited by the lack of supporting data and high operational resource requirements. On the other hand, users of the more simple methods might not be aware of the underlying assumptions that tend to limit the applicability of these approaches.

Based on our review of the 20 ecological assessment methods, ICF and the reviewers of our draft report have several recommendations:

- Government-sponsored ecological damage assessments (field investigations conducted to assess existing ecological damage) provide an excellent opportunity for collecting data on the relationship between pollutant levels and ecological damage. Agency program offices should coordinate their efforts in this regard to take full advantage of this data source.

- Additional laboratory and field research is needed in several areas: the interactions between stressors; sublethal effects; uncertainties associated with extrapolation of laboratory data to the field; and modeling of population responses to pollutants considering density-dependent population interactions.

- More emphasis should be placed on exposure-response evaluation, with less emphasis on identifying "no effect levels" based on hypothesis testing. In addition, more emphasis should be placed on statistical treatment of uncertainty.

- Endpoints should be chosen based on ecological, societal, and regulatory significance as well as on data availability. Although endpoints such as species diversity, altered nutrient cycling, and ecosystem resilience may be more significant ecologically than endpoints such as mortality, theoretical constraints and the lack of exposure-response data currently limit the applicability of ecosystem-level endpoints to most problems.

1.0 INTRODUCTION

1.1 PURPOSE OF THE REPORT

This report reviews several existing methods developed by EPA and other Federal and state agencies for assessing ecological impacts or risks associated with the release of toxic or hazardous substances into the environment. The purpose of this report is to identify general trends and limitations of ecological assessment methods as they are currently employed. This document is not intended to provide a step-by-step approach for conducting ecological assessments, but to provide a baseline understanding of the processes and general applications of ecological assessment methodologies.

1.2 GENERAL APPROACH AND SCOPE

We reviewed several existing ecological assessment methods to identify technical approaches to ecological assessment and to place these approaches in the context of solutions to particular needs, such as developing standards or establishing testing priorities. To ensure a consistent approach to each review, we developed a framework for the description of each method. Our reviews were structured to address the four basic components of ecological risk assessment illustrated in Figure 1: (1) receptor characterization, (2) hazard assessment, (3) exposure assessment, and (4) risk characterization. We also described the operational resources (e.g., cost, level of expertise) required to implement each approach.

Our review is limited to methods that we consider representative of those in use by state or Federal agencies, or methods that are ready to be implemented; we do not include those that are still experimental. We focus on methods designed to predict the possibility or probability of adverse ecological impacts. Methods designed to quantify existing damages or those used to model exposure are included only in terms of their contribution to predicting adverse ecological effects.

To understand the methods in the context of their intended application, we also review the legislative or executive directives under which the methods were developed. Table 1 shows the legislative mandates considered, the methods developed under each, and a brief summary of the purpose of each method. Some of the methods covered in this document were not developed under any specific legislative mandate, but are included because they were developed for EPA use or had been used by EPA offices; these are presented in Table 2. For simplicity, we refer to methods in this report by the government office for which the method was prepared. The exceptions to this are some of the methods which were not developed under

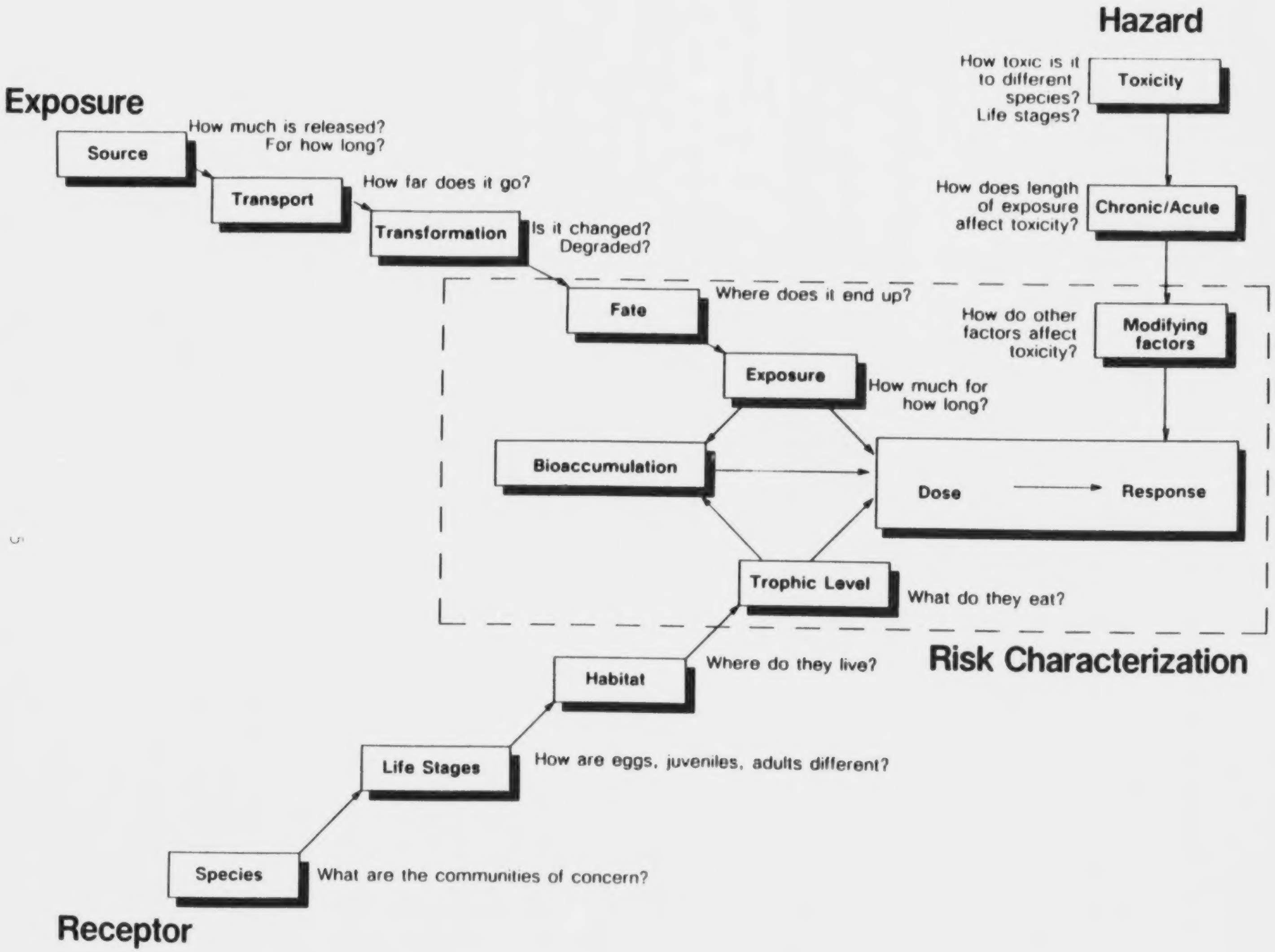
Hazard
Exposure
How much is released? For how long?
Source
Transport
How far does it go?
Transformation
Is it changed? Degraded?
How toxic is it to different species? Life stages?
Toxicity
How does length of exposure affect toxicity?
Chronic/Acute
Fate
Where does it end up?
How do other factors affect toxicity?
Modifying factors
Exposure
How much for how long?
Bioaccumulation
Dose
Response
Trophic Level
What do they eat?
Habitat
Where do they live?
Risk Characterization
Life Stages
How are eggs, juveniles, adults different?
Species
What are the communities of concern?
Receptor

FIGURE 1. AN INTEGRATED MODEL FOR ECOLOGICAL RISK ASSESSMENT

TABLE 1: STATUTES, DIRECTIVES, AND ASSOCIATED METHODS REVIEWED

METHOD NO	STATUTE OR DIRECTIVE	MANDATE	METHOD	BRIEF DESCRIPTION OF OBJECTIVE
	Legislation Administered by EPA			
1-	Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, including the 1986 amendments)	To establish a National program for responding to releases of hazardous substances into the environment.	Measuring Damages to Coastal and Marine Environment Natural Resources (DOI 1987a)	To establish procedures for assessing damages to natural resources from a relatively small discharge of oil or a release of a hazardous substance.
2-			Natural Resource Damage Assessments. Final Rule (for Type B Assessments) (DOI 1987b)	To establish procedures for assessing damages to natural resources from a relatively large discharge of oil or a release of a hazardous substance.
3-	Clean Air Act	To protect and enhance the quality of the Nation's air resources through the prevention and control of air pollution.	Review of the National Ambient Air Quality Standards for Ozone (EPA/OAR 1986)	To assess the risks of ozone to human welfare.
4-			An Assessment of the Risk of Stratospheric Modification (EPA/OAR 1987)	To assess the ecological impacts of chemicals that modify the stratosphere.
5-	Clean Water Act (including the Water Quality Act of 1987)	To restore and maintain the chemical, physical, and biological integrity of the Nation's waters.	Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and their Uses (EPA/OWRS 1986)	To standarize a method for deriving guidelines for chemical concentrations consistent with the protection of aquatic organisms, human health and some recreational activities.
6-			An Approach to Assessing Exposure to and Risk of Environmental Pollutants (EPA/OWRS 1983)	To provide guidelines for conducting risk assessments for waterborne pollutants.
7-			Water Quality-Based Permitting for Toxic Pollutants (EPA/OWRS 1985, 1987)	To provide guidelines for issuing National Pollutant Discharge Elimination System (NPDES) permits.
8-			Biological Criteria for the Protection of Aquatic Life (Ohio EPA 1987a,b, 1988)	To standardize collection and use of biological measures of surface water quality.
9-			Nigara River Biota Contamination Project: Fish Flesh Criteria for Piscivorous Wildlife (NYS/DEC 1987)	To develop limits for fish tissue residues levels protective of fish-eating wildlife.
10-	Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	To prevent "unreasonable adverse effects on the environment" from the misuse of pesticides.	Standard Evaluation Procedure for Ecological Risk Assessment (EPA/OPP 1986)	To outline procedures to assess risk of pesticide uses proposed for registration.
11			Chemical Migration Risk Assessment (Onishi et al. 1982, 1985)	To predict the occurrence and duration of pesticide concentrations in surface receiving agricultural runoff and to predict the potential damage to aquatic biota.

TABLE 1: STATUTES, DIRECTIVES, AND ASSOCIATED METHODS REVIEWED (continued)

METHOD NO.	STATUTE OR DIRECTIVE	MANDATE	METHOD	BRIEF DESCRIPTION OF OBJECTIVE
	Marine Protection and Resources Sanctuaries Act	To regulate the disposal of waste in the ocean in order to protect human health, welfare, and amenities, and the marine environment, ecological systems, and economic potentialities.	We have not identified any methods developed under this legislation.	
12-	Resource Conservation and Recovery Act (RCRA)	To promote the protection of health and the environment and to conserve valuable material and energy sources.	Potential for Environmental Damage: Proximity of Mine Waste Sites to Sensitive Environments (EPA/OSW 1987a)	To aid in screening different mining activities for potential environmental impacts.
13-			Technical Resource Document for Risk-based Variances from the Secondary Containment Requirement of Hazardous Waste Tank Systems. Volume II: Risk-based Variance. (EPA/OSW 1987b)	To determine environmental risks posed by the release of waste constituents from hazardous waste tanks.
14-			The RCRA Risk-Cost Analysis Model, Phase III Report (EPA/OSW 1984)	To aid in designing regulations governing hazardous waste treatment that are protective of human health and the environment.
	Safe Drinking Water Act	To assure that all public drinking water systems provide safe, high quality water.	We have not identified any methods developed under this legislation.	
15-	Toxic Substances Control Act (TSCA)	To protect human health and the environment through the regulation of the manufacture and use of chemicals.	Estimating "Concern Levels" for Concentrations of Chemical Substances in the Environment (EPA/OTS 1984)	To aid in the evaluation of premanufacturing notices for new chemicals which may or may not be toxic or released into the environment.
16-			Ecological Risk Assessment in The Office of Toxic Substances: Problems and Progress 1984-1987 (EPA/OTS 1987)	To define potential hazards posed by toxic chemicals.
Legislation Administered by Other agencies				
	Coastal Zone Management Act of 1972	To encourage and assist States to develop and implement mangement programs to protect the land and water resources of the coastal zone.	We have not identified any methods developed under this legislation.	
	Endangered Species Act	To conserve the ecosystems upon which endangered or threatened species depend, and to conserve the species themselves.	We have not identified any methods developed under this legislation.	
	Executive Order 11988, Floodplain Management	Requires that Federal agencies take actions to reduce the risk of flood loss, and to restore and preserve the natural and beneficial values served by floodplains.	We have not identified any methods developed under this legislation.	

TABLE 1: STATUTES, DIRECTIVES, AND ASSOCIATED METHODS REVIEWED (continued)

METHOD NO.	STATUTE OR DIRECTIVE	MANDATE	METHOD	BRIEF DESCRIPTION OF OBJECTIVE
	Executive Order 11990, Protection of Wetlands	Requires that Federal agencies take actions to minimize the destruction, loss, or degradation of wetlands, and to preserve and enhance the natural and beneficial values served by wetlands.	We have not identified any methods developed under this legislation.	
	Fish and Wildlife Coordination Act	To assist in developing and protecting all species of wildlife, wildlife resources, and wildlife habitat.	We have not identified any methods developed under this legislation.	
	National Environmental Policy Act (NEPA)	To preserve and enhance the environmental quality of the Nation.	We have not identified any methods developed under this legislation.	
	Wild and Scenic Rivers Act	To preserve selected rivers in their free-flowing condition, to protect the water quality of such rivers, and to fulfill other vital national conservation purposes.	We have not identified any methods developed under this legislation.	

TABLE 2

ADDITIONAL METHODS REVIEWED

METHOD NO	METHOD	BRIEF DESCRIPTION OF OBJECTIVE
17-	Methodology for Environmental Risk Analysis (Barnthouse 1982); Users Manual for Ecological Risk Assessment (Barnthouse et al. 1986)	To support EPA/ORD's synfuels research program by developing an environmental risk assessment methodology.
18-	Regional Ecological Assessments: Concepts, Procedures and Application (Ballou et al. 1981)	To discuss the approaches developed at Argonne National Laboratory to conduct regional ecological assessments for the impacts of alternative energy options.
19-	Computer Simulation Models of Assessment of Toxic Substances (Eschenroeder et al. 1980)	To develop a comprehensive chemical fate and transport simulation model which includes transport through the biotic environment.
20-	Unfinished Business: A Comparative Assessment of Environmental Problems	To estimate and rank current ecological risks posed by 31 environmental problems.

any specific legislation. More detailed information describing authors is given, when available, in Appendix C and in the references. A quick reference guide to Appendix C is provided in Table 3.

1.3 DEFINITIONS

Because ecological impact and risk assessment are still emerging fields, a wide variety of terms and definitions have been used to describe different types of analyses. In this document, we use the term "ecological assessment" to refer to any type of assessment related to actual or potential ecological effects resulting from human activities. The term therefore encompasses impact, risk, and damage assessments as well as the establishment of environmental criteria based on ecotoxicology.

The phrase "ecological risk assessment" is commonly used to cover this array of analyses. In strict usage, however, ecological risk assessment is a quantitative procedure that estimates the probability of specified levels of ecological effects occurring in an ecosystem or part of an ecosystem in response to a perturbation, and relates the magnitude of the impact to the perturbation. In order to distinguish this more strict usage of the word "risk," we refer to this latter type of analysis as "ecological risk assessment" in this document and to all other analyses as "ecological assessments."

1.4 ORGANIZATION OF THE REPORT

The remainder of this report presents the major findings of our review. In Section 2.0, we discuss the general purposes of ecological assessments and the approaches currently used. We discuss our general conclusions and recommendations for future developments in the area of ecological risk assessment in Section 3.0. A glossary that includes terms used in the text and appendices follows the text. Appendix A describes our approach to reviewing the different methods and presents the framework used for each review. Appendix B summarizes the requirements of 15 legislative or executive directives for ecological assessments. Finally, Appendix C presents the results of our detailed discussion of each method.

TABLE 3

GUIDE TO METHODS REVIEWED IN APPENDIX C

Method No.	Method	Pages
1 -	CERCLA Type A Damage Assessment (DOI 1987a)	C- 2- 9
2 -	CERCLA Type B Damage Assessment (DOI 1987b)	C-10-13
3 -	Ozone Staff Paper (EPA/OAR 1986)	C-14-16
4 -	Stratospheric Modification (EPA/OAR 1987)	C-17-21
5 -	Ambient Water Quality Criteria (EPA/OWRS 1986)	C-22-24
6 -	Approach to Exposure and Risk (EPA/OWRS 1983)	C-25-27
7 -	Water Quality-based Permitting (EPA/OWRS 1985, 1987)	C-28-31
8 -	Biological Criteria (Ohio EPA 1987a, 1987b, 1988)	C-32-38
9 -	Niagara River Fish Flesh Criteria (NYS/DEC 1987)	C-39-41
10 -	Standard Evaluation Procedure for Ecological Risk (EPA/OPP 1986)	C-42-46
11 -	Chemical Migration Risk Assessment (Onishi *et al*. 1982, 1985)	C-47-51
12 -	Proximity to Sensitive Environments (EPA/OSW 1987a)	C-52-53
13 -	HWT Risk-based Variance (EPA/OSW 1987b)	C-54-56
14 -	RCRA - Risk Cost Analysis Model (EPA/OSW 1984)	C-57-60
15 -	Estimating Concern Levels (EPA/OTS 1984)	C-61-62
16 -	Ecorisk in OTS (EPA/OTS 1987)	C-63-66
17 -	Users' Manual for Eco. Risk (Barnthouse *et al*. 1982, 1986)	C-67-78
18 -	Regional Ecological Assessments (Ballou *et al*. 1981)	C-79-86
19 -	Computer Simulation Model (Eschenroeder *et al*. 1980)	C-87-88
20 -	Comparative Risk Project (EPA/OPPE 1987)	C-89-92

2.0 DISCUSSION OF METHODS

In this section, we discuss the major findings of our review. In Section 2.1, we identify several objectives of ecological assessments, and provide examples of methods developed for each objective. In Section 2.2, the methods are grouped broadly by the type of approach used. Finally, the technical content of each method is discussed in Section 2.3.

2.1 OBJECTIVES OF METHODS

All of the methods included in our review were developed to assess the potential for adverse effects on ecosystems or parts of ecosystems from the release of hazardous substances into the environment. Within this overall intent, however, the methods were developed for several practical applications. The objectives of an ecological assessment method depend, in part, on the legal mandate under which the method was developed. Most of the legal mandates require consideration of "human health and the environment". However, some mandates more specifically request the development of standards or guidelines to limit concentrations of hazardous substances in the environment (e.g., the Clean Water Act specifies the "development of federal water quality criteria"). In other situations (e.g., energy development, pesticide use), adverse ecological effects must be weighed against the benefits to human welfare. In these cases, a quantitative ecological risk assessment may be used for comparing incremental costs and benefits. Prioritization schemes have been developed to aid decision makers in narrowing the large scope of regulatory concerns and to target situations that require more testing or research.

The specific objectives of each method are summarized in Tables 1 and 2. In general, we found that most methods have one of three objectives: (1) to set priorities, (2) to support the setting of standards or guidelines, and (3) to assess risk as input to risk management decisions. While some of the methods were developed specifically for one of these objectives, several of them could be easily applied to more than one objective.

Several of the methods included in our review are ranking schemes used to set priorities. For example, the Comparative Risk Project (EPA/OPPE 1987) ranks broad environmental problems. The RCRA Risk-Cost Analysis Model (EPA/OSW 1984) scores hazardous waste treatment, storage, and disposal technologies with respect to their relative potential for producing adverse ecological impacts. Other ecological assessment methods have been used as screening procedures to identify priorities for further testing or research. For example, the Standard Evaluation Procedure (SEP) for Ecological Effects (EPA/OPP 1986) and the Method for Estimating Concern Levels (EPA/OTS 1984) identify chemicals which, by their projected pattern of release into the environment, are of sufficient ecological concern to merit further testing. The Approach for Assessing Exposure and Risk developed by EPA/OWRS (1983) describes a method of identifying combinations of plant and animal species, exposure levels, and projected effects on a site-specific basis that are of sufficient ecological concern to merit further investigation. Similarly, EPA/OSW (1987a) screened mine sites for the potential to adversely affect valuable ecosystems based on to their proximity to sensitive habitats. One well-known priority setting method that we did not review is the Hazard Ranking System (HRS), which is used to select sites for the Superfund National Priorities List. This is because the current version of the system has a very limited ecological assessment component, and the proposed revisions are not available for public comment at the time of this publication.

Several of the methods reviewed were developed to assist in setting standards or guidelines to limit releases of chemicals into the environment. The Ambient Water Quality Criteria methodology has been used to set guidelines for limiting ambient pollutant concentrations in surface water to be protective of aquatic life. The Water Quality-based Permitting for Toxic Pollutants (EPA/OWRS 1985, 1987) approach establishes guidelines for using whole-effluent toxicity tests to establish effluent discharge limits. In the Ozone Staff Paper (EPA/OAR 1986), EPA estimated concentrations of ozone in the atmosphere that should be protective of agricultural plants and forests. As an approach to calculating acceptable release levels of chemicals, the EPA/OTS (1984) method to estimate Concern Levels identifies concentrations of chemicals that may cause adverse environmental effects in aquatic populations. The NYS/DEC (1987) used the Niagara River Fish Flesh Criteria methodology to set limits for contaminant residue levels in fish that would be protective of piscivorous animals such as mink and osprey.

Most of the remaining methods were developed to conduct risk assessments to support management decisions (e.g., Onishi *et al*. 1985, EPA/OSW 1987b, EPA/OAR 1987). Of these, only the Land-Use Disturbance portion of the Regional Ecological Assessments method (Ballou *et al*. 1981) and the Stratospheric Ozone analysis (EPA/OAR 1987) evaluates risks associated with agents other than toxic chemicals. The User's Manual for Ecological Risk Assessment (Barnthouse *et al*. 1986) includes several methods that can be used to support standard and priority setting as well conducting quantitative risk assessments.

Three of the methods included in our review assess existing ecological impacts. The Type B damage assessment (DOI 1987b) includes methods to measure ecological damages that have already occurred. Although damage assessment is not the focus of this report, these methods can provide information that can be used as a baseline for predictive risk assessment, and can offer insight into the appropriate receptors, endpoints, and exposure pathways to be used in risk assessment. The Type A damage assessment procedure (DOI 1987a) was developed to estimate damage, but can be applied to predicting the occurrence of adverse effects. The Ohio EPA (1987a, 1987b, 1988) Biological Criteria and evaluation methodology includes measurements of fish and macroinvertebrate sub-communities that reflect the biological integrity of aquatic ecosystems.

Other methods, such as Regional Assessment Units (Ballou et al. 1981), were developed to provide a common basis for discussion and are included in our review only in the context of their contribution to risk assessment.

2.2 TYPES OF METHODS AND APPLICABILITY TO OBJECTIVES

In this section, we discuss the general types of methods reviewed, some of the strengths and weaknesses of each, and their suitability for the objectives discussed above.

2.2.1 Qualitative vs. Quantitative Methods

Although most of the methods reviewed are based on quantitative analyses, several use qualitative analyses, as discussed below.

Qualitative Methods. One of the qualitative methods described in Ballou et al. (1981) was designed to identify potential conflicts in implementing certain energy resource development scenarios by delineating endangered and threatened species habitat. The EPA/OSW (1987a) used a similar approach in "Proximity of Mine Waste Sites to Sensitive Environments". In this analysis, mine sites in different mining segments were identified as posing more or less of a threat to highly valued environments based on their proximity to endangered species habitats, wetlands, and National parks and forests.

Two of the qualitative methods, EPA/OPPE (1987) and EPA/OWRS (1983) use professional judgment to evaluate ecological effects. The Comparative Risk Project (EPA/OPPE 1987) used professional judgment to broadly rank a large diversity of environmental problems. Similarly, in the OWRS approach to exposure and risk (EPA/OWRS 1983), a great deal of professional judgment is used to identify specific surface water locations that should be further investigated because of a high potential for adverse ecological effects.

The strength of qualitative approaches is that they can be used to evaluate effects and problems for which there is little quantitative information. By using professional judgment, many levels of information can be integrated into the decision-making process. The qualitative methods included in our review illustrate that these methods can be used effectively to set priorities, either as screening or ranking procedures. Qualitative methods, however, are limited in their use for either developing standards or managing risks. The effort required to implement qualitative methods can be low relative to quantitative computer-based models. However, if the methods that rely on professional judgment are to yield useful results, the assessors must be highly skilled.

Quantitative Methods. The quantitative methods reviewed can be categorized as quotient or ratio methods (illustrated in Figure 2) and continuous or exposure-response methods (illustrated in Figure 3).

FIGURE 2

QUOTIENT METHOD

$$\text{IF } \frac{\text{EEC}}{\text{LC}_{50}} \times \text{AF} \geq 1\text{, regulate.}$$

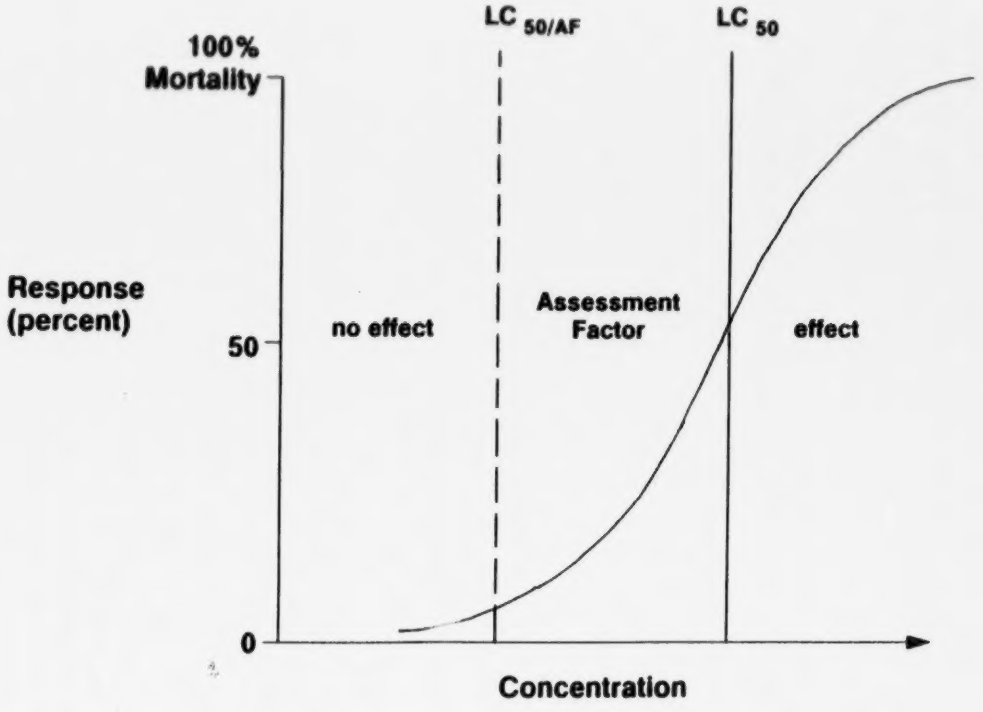

Figure 2. One use of the quotient method is to compare an estimated environmental concentration (EEC) to a toxicity benchmark (e.g., LC_{50}). Generally a few percent mortality is considered acceptable, and the LC_{50} is multiplied by an assessment factor (AF) to estimate the level above which more than a few percent mortality would occur. If the $EEC/LC_{50} \times AF$ equals or exceeds 1, then a decision to regulate the chemical or to investigate the situation more fully is made.

FIGURE 3

EXPOSURE-RESPONSE METHOD

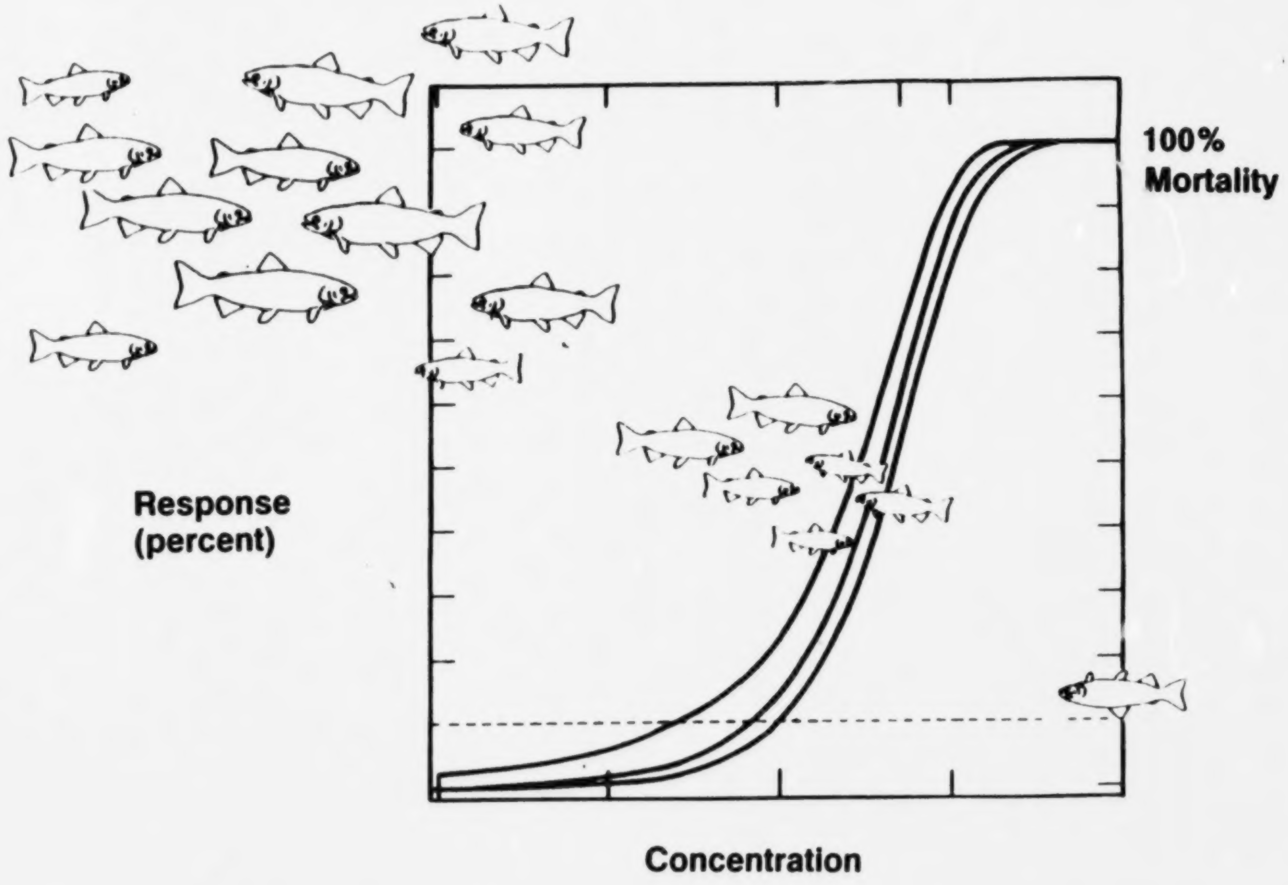

Figure 3. In the exposure-response method, estimated environmental concentrations are used to predict the level of response (e.g., 40 percent mortality). Confidence limits around the exposure-response curve define the uncertainty associated with the predicted level of response.

Quotient Methods:

Quotient methods are used to determine whether or not a specified level of environmental contamination might be of ecological concern. Reference concentrations intended to be protective of a given receptor are established and are compared with estimated environmental concentrations (EECs). For example, as illustrated in Figure 2, an "assessment factor" (AF) can be applied to an acute LC_{50} value[1] (solid vertical line, Figure 2) to estimate a reference concentration that is approximately equivalent to a LC_1 value (dashed vertical line, Figure 2). Environmental concentrations that exceed the reference concentration are considered to have potential adverse effects.

Several of the methods that we reviewed use the quotient method, including EPA/OPP's (1986) Standard Evaluation Procedure for Ecological Risk Assessment, EPA/OTS's (1984) method for Estimating 'Concern Levels', and EPA/OSW's (1987b) method of evaluating risk from hazardous waste tanks.

Quotient methods provide essentially a "yes or no" determination of risk and are therefore well-suited for screening-level assessments. In these cases, a decision concerning the level of risk that is considered acceptable is required, but is contained within the derivation of a reference criterion concentration. For example, the AWQC method (EPA/OWRS 1986) assumes that 1 percent adult mortality is an acceptable acute effect and that 5 percent of the species present in an ecosystem can suffer more than 1 percent adult mortality without the expectation of adverse ecosystem effects.

The primary advantage of the quotient method is that it is a relatively low cost, easily implemented method that often relies on data that are readily available for many chemicals (e.g., LC_{50}, LD_{50} values). Consequently, quotient methods are well-suited for setting priorities as well as for developing standards.

A limitation of the quotient method is that it does not predict the degree of risk or magnitude of effects associated with specified levels of contamination. This is a minor limitation when setting standards or priorities. Some of the methods, however, attempt to address this problem; these can be called "modified quotient methods." In Barnthouse _et al_.'s (1986) Quotient Method and in EPA/OSW's (1987) Risk-based Variance procedure, the conclusions are expressed as "no concern", "possible concern", and "high concern", depending on whether the ratio of the estimated environmental concentration (EEC) to the reference concentration is <0.1, 0.1 to <10, or >10, respectively. Another modification of the quotient method was used by Onishi et al. (1985); in this method, EECs were compared to Maximum Acceptable Toxicant Concentrations (MATCs)[2] and LC_{50}s. If the EEC was below the MATC, the fish population was considered "safe". If the EEC was above the LC_{50}, the fish population was believed to be at risk of increased mortality. If the EEC was between the MATC and the LC_{50}, the fish population was considered to be at risk of sublethal effects.

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[1] An LC_{50} value is the concentration of a substance in water that is associated with the death of 50% of the organisms in a laboratory bioassay. This notation is also used to describe other proportions; for instance, LC_1 refers to the concentration estimated to kill 1 percent of the test organisms. Similarly, an LD_{50} value is the dose (usually expressed as mg/kg body weight) that is estimated to kill 50 percent of the test organisms.

Exposure-Response methods:

Exposure-response or continuous approaches are used to estimate the magnitude of effect associated with an estimated exposure concentration. The full exposure-response curve is used to estimate risk. For example, one could use an exposure-response curve (illustrated in Figure 3) to estimate the exposure concentration expected to produce 10, 20, 50, or 100 percent reduction of a trout population due to direct effects of a contaminant.

Derivation of explicit risk estimates for a given endpoint of concern requires, at a minimum, relating estimated environmental concentrations to exposure-response information. An example of the use of exposure-response information to estimate population-level effects is Ballou et al.'s (1981) assessment of the effects on crop productivity of atmospheric sulfur dioxide released from fossil fuel burning plants. In this approach, the concentration of SO_2 at varying distances from the emission source was modeled and compared with dose-response data for SO_2-induced reductions in crop yields. The estimated losses in crop productivity were then mapped spatially to provide an estimate of the areal extent and degree of crop reduction with increasing distance from the source of air emissions.

The exposure-response approach is well-suited for situations in which an estimate of the magnitude of risk estimated to occur is needed to support the setting of a standard, or in cases where a risk management analysis will be conducted. For example, the EPA/OAR (1986) used an exposure-response approach to aid in setting standards. Exposure-response data were used to estimate crop yield reductions with increasing ambient ozone concentrations. EPA/OAR selected a 10 percent reduction in yield as the level of concern. The selection of a particular level of effect represents a risk management decision. The exposure-response approach allows a decision-maker to choose a level of concern based on economic and human welfare considerations if necessary. In this way, the exposure-response approach may be more useful for providing input to risk management decisions than the quotient method.

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[2] The MATC is the toxic chemical threshold concentration lying in a range bounded at the lower end by the highest concentration having no effect (NOEL) and at the higher end by the lowest test concentration having a significant toxic effect (LOEL) in a life cycle or partial life cycle test.

The exposure-response approach has also been used, in the case of the RCRA Risk-Cost Analysis Model (EPA/OSW 1984), to aid in setting priorities. Thus, one of the strengths of this approach is that it can be applied to many purposes. A limitation of the approach, however, is that exposure-response data are not available for many chemical/receptor combinations.

2.2.2 "Top-Down" vs. "Bottom-Up" Methods

Most of the dose-response or quotient methods in our review addressed effects to individuals or populations. There are two ways to approach the evaluation of effects at the community and ecosystem level. The first approach, called the "top-down" approach, directly assesses changes in function and structure of communities and ecosystems (e.g., alterations in species diversity or primarily production rates). The second approach, the "bottom-up" approach, uses laboratory data on effects at lower levels of organization (e.g., mortality of individuals) to model changes at the community or ecosystem level.

Top-down Methods. Several of the methods reviewed could be called top-down methods. These include EPA/OPPE's (1987) Comparative Risk Project, the RCRA Risk-Cost Analysis Method (EPA/OSW 1984), EPA/OSW's (1987a) Sensitive Environment analysis, Ballou *et al*.'s (1981) Land-use Disturbance and Endangered and Threatened Species, and Ohio EPA's (1987a, 1987b, 1988) Biological Criteria methods. Most of these methods were used to aid in setting priorities, however, and none included an ecosystem-level exposure-response analysis.

One of the strengths of top-down approaches is that they evaluate changes in communities and ecosystems directly. These changes, as opposed to such effects as changes in the number of individuals in the population of a single species, are easily defended by decision-makers as being important. However, at the present time, few data exist to directly predict the effects of chemicals on ecosystem-level properties such as structure and function. More fundamentally, there is no accepted definition of "ecosystem health," in part because ecosystems are dynamic, changing with environmental conditions as organisms adapt or adjust to stress (EPA/OPPE 1987). Thus, most of the predictive top-down approaches that we reviewed either address habitat alteration or are based on professional opinion.

The Ohio EPA (1987a, 1987b, 1988) Biological Criteria and evaluation methodology represents a top-down approach to evaluating existing ecological impacts. The criteria are biological indices based on several measures of fish and macroinvertebrate community structure (e.g., species diversity, species number) that reflect the biological integrity of aquatic ecosystems. In this case, "ecosystem health" is defined as the value of the indices measured for "least impacted" surface water bodies in each of several ecoregions in the state.

The RCRA Risk-Cost Analysis Model (EPA\OSW 1984) is an example of a top-down predictive approach that attempts to be quantitative. In this approach, a generic ecosystem exposure-response curve is constructed, spanning concentrations corresponding to minimal effects on sensitive species at the lower end to ecosystem-level catastrophic effects at the high end. The curve was based on four studies in which an ecosystem-level exposure-response relationship could be constructed empirically. Hence, there are many uncertainties associated with applying this curve to other chemicals or situations.

Because of the lack of toxicological data available for directly evaluating changes in communities or ecosystems, quantitative risk assessment cannot currently be conducted in a "top-down" manner, with very few exceptions. However, as illustrated by the methods we reviewed, top-down approaches can be used effectively in setting priorities.

Bottom-up Methods. Three of the methods included in our review (DOI 1987a, Eschenroeder et al. 1980, Barnthouse et al. 1986) could be called "bottom-up" methods. These methods estimate community-level effects using computer models and laboratory data on the responses of individuals and populations to chemicals. One of the strengths of bottom-up approaches is that they provide insight into the processes that transfer effects between different components of ecosystems (e.g., through a food web). However, because these models require a great deal of site- and chemical-specific data, the bottom-up approaches are most useful in supporting risk management decisions on a site-specific basis.

The theoretical constraints of the modeling approaches can be daunting. The ecological theory required to use system analysis to predict changes in communities and ecosystems from more basic information is still in its infancy, despite early recognition of its importance (Kickert and Miller 1979). Although the models that attempt to predict community responses using individual and population-level laboratory data illustrate the substantial progress that has been made in ecological risk assessment, they may not incorporate (for practical or theoretical reasons) responses that can greatly influence the conclusions drawn about risk. At least one of the three methods that model biotic community-level effects considers each of the following biotic community relationships:

- Transfer of energy and biomass from primary productivity through several trophic levels and transfer of toxicant-induced reductions in productivity at one trophic level through successive levels;

- Effects of reduced recruitment of juveniles to population age-structure, productivity, and biomass;

- Transfer of toxicants through several trophic levels; and

- Changes in respiration, feeding, or grazing rates, susceptibility to predation, mortality, emigration, and fecundity in species at one trophic level affecting species in successive trophic levels.

However, none of the three methods appear to consider other important factors influencing community response:

- Density-dependent population regulation (e.g., density-dependent changes in juvenile survivorship compensating for mortality caused by pollution);
- Toxicant-induced changes in behavior (e.g., avoidance, disrupted chemical communication among animals); and
- Incorporation of biotic and abiotic stressors (e.g., parasites and extreme weather, respectively) and toxicant-induced changes in responses to these stressors.

2.3 TECHNICAL CHARACTERISTICS

We reviewed each ecological assessment method with respect to five broad factors: (1) receptor characterization, (2) hazard assessment, (3) exposure assessment, (4) risk characterization, and (5) operational resource requirements. Our detailed framework for reviewing the methods is presented in Appendix A, and the results of our review of each method are found in Appendix C. In this section, we discuss four major technical characteristics that appear to be particularly important in determining the scope and results of ecological assessment as it is currently practiced. In general, the technical characteristics of ecological assessment methods are similar for methods that were developed for similar objectives (e.g., setting standards) or that are based on the same general type of approach (e.g., quotient method, exposure-response approach). Therefore, we discuss the technical characteristics of the methods in the context of the overall objectives for which the methods were designed.

2.3.1 Definition of Receptors and Endpoints

Receptors are the components of ecosystems that are or may be adversely affected by a pollutant or other stress. Endpoints are the particular types of impact or potential impact a chemical or other environmental stress has on a receptor (e.g., death, decreased growth or productivity). Because of the complexity of natural systems, it is difficult to assess potential impacts to all receptors for all endpoints. Therefore, ecological assessment methods select particular types of receptors and endpoints to be "indicators" of potential harm to all components of the system.

The range of potential indicators is enormous. Table 3 presents a list of some potential endpoints for receptors at the individual, population, community, and ecosystem level. Although there is no accepted definition of ecosystem "health", some possible indicators of ecosystem resilience (the ability of an ecosystem to recover from stress) include measurements of species diversity, nutrient cycling, and productivity at the community or ecosystem level (Levin *et al*. 1983, NRC 1981, EPA/OPPE 1987). Because there is general consensus on adverse effects at the population level, (e.g., decreased reproduction or growth, increased mortality), the most appropriate endpoints for use in risk assessment at this time may be at the population level.

Few of the methods reviewed selected receptors and endpoints based solely on ecological significance. In fact, in most cases the selection is driven by practicality, as the receptors and endpoints selected tend to be those for which the most toxicity data are available. For example, most of the methods assess aquatic receptors. Part of the reason for this is that there is generally less information on the exposure of terrestrial organisms, or on the toxic effects of chemicals to terrestrial organisms. The particular approaches to receptor and endpoint selection under the various types of methods are discussed below.

Methods Used to Develop Standards or Guidelines. Of the ecological assessment methods used to develop standards, the most common endpoints selected were laboratory measurements of acute or chronic toxicity at the species level. Most often the endpoint of concern for short duration exposures is death. For longer duration exposures, the endpoints of concern are ususally reduced growth, reproduction, and survival of sensitive life-stages. Sublethal effects such as altered respiration and behavior are seldom considered, although these types of impacts can have substantial consequences for populations as well as for communities and ecosystems.

Typically, toxicity data for a sensitive effect (endpoint) and a sensitive species (receptor) are selected, if possible, to represent the ecosystem as a whole, although other factors such as the type, source, and release pattern of the chemical, and potential pathways for fate and transport through the environment, are also considered. The general assumption is that if a most sensitive species is protected from direct toxic effects of a chemical or effluent, the ecosystem will not be adversely affected (EPA/OWRS 1986). It is often necessary, however, to use species that can be tested reliably in the laboratory (EPA/OWRS 1985).

The use of indicator species to represent the ecosystem is often the approach taken in developing standards because it allows expeditious review of a large number of chemicals, which often is required for chemical regulatory programs. However, this approach is limited because endpoints are selected based on the most sensitive effects in laboratory species; sensitive effects in field populations may be different or may be altered by density-dependent interactions in the field. Figure 4 describes some of the factors that influence differences between field and laboratory population responses to toxic chemicals.

Ohio EPA, however, has developed Biological Criteria for surface water quality that are measures of fish and invertebrate community structure (Ohio EPA 1987a, 1987b, 1988). The criteria are based on the values of the community indices measured in reference environments selected as examples of "least impacted" surface water bodies in each of several ecoregions in the state. This approach avoids many of the sources of error associated

TABLE 4

POSSIBLE ENDPOINTS FOR ECOLOGICAL RISK ASSESSMENT

INDIVIDUALS
- Change in respiration
- Change in behavior (e.g., avoidance of contaminated areas)
- Inhibition or induction of enzymes
- Increased susceptibility to pathogens
- Decreased growth
- Death (particularly important in the case of endangered species, where the loss of even one individual is considered significant)

POPULATIONS
- Decreased genotypic and phenotypic diversity
- Decreased biomass
- Increased mortality rate
- Decreased fecundity
- Decreased recruitment of juveniles
- Increased frequency of disease
- Decreased yield
- Decreased growth rates

COMMUNITIES
- Decreased species diversity
- Decreased food web diversity
- Decreased productivity
- Increased algal blooms

ECOSYSTEMS
- Decreased diversity of communities
- Altered nutrient cycling
- Decreased resilience

FIGURE 4

EXTRAPOLATION FROM LABORATORY TO FIELD -
DIFFERENCES BETWEEN LABORATORY STUDIES AND FIELD CONDITIONS

Parameter	Laboratory Bioassay	Field Exposure
Chemical Characteristics Concentrations	• usually exposed to one chemical • well-defined • can be measured • system is well-mixed	• usually exposed to a mixture • can be measured, but often are estimated • highly variable, system is usually not well mixed
Organisms Genetic variation Interaction Behavior	• usually use selected genetic strain • usually one species is exposed • number of organisms is usually controlled • organisms cannot avoid exposure	• high natural variability • many species present • density-dependent population fluctuations • organisms can avoid exposure, emigration/immigration possible
Environment Toxicity modifying factors	• parameters closely controlled	• parameters highly variable, uncontrolled

with extrapolating from the laboratory into the field; however, it is not always possible to identify the source of observed degradation of the biological communities.

Methods Used to Set Priorities. Ecological assessment methods that are used to set priorities also often use the indicator species approach because the approach relies on readily available data (often LC_{50}s or LD_{50}s) and provides a common base (the indicator species and endpoint) by which all chemicals can be compared. A few of the priority-setting methods reviewed (EPA/OSW 1984, 1987a, EPA/OPPE 1987) explicitly characterized receptors at a community or ecosystem level (e.g., wetlands, rivers, forests). However, this approach is used less frequently because the data base available to relate chemical stresses to changes in communities and ecosystems is extremely limited and situation-specific. Therefore, assessments of ecological impacts or potential impacts tend to be limited to qualitative evaluations (EPA/OSW 1987a, EPA/OPPE 1987) or are based on broad assumptions regarding the relationship between effects at the species and ecosystem levels (EPA/OSW 1984).

Methods Used to Assess Risk for Risk Management Decisions. Most of the methods used for quantitative risk assessment characterize receptors and endpoints at the species or population level, in part because of the more extensive data base on toxic effects at these levels. In an effort to identify ecologically important endpoints that might otherwise be overlooked (e.g., avoidance of spawning areas), EPA/OTS (1987) includes a fault tree analysis in their method.

A few of the methods used for risk assessment and risk management have attempted to select receptors and endpoints at the community and ecosystem level based on ecological significance. The NAAQS review of ozone effects (EPA/OAR 1986) and the stratospheric modification assessment (EPA/OAR 1987) discuss community and ecosystem-level effects qualitatively. Some of the more recent computer models also have attempted to model effects at the community and ecosystem level (Barnthouse *et al*. 1986, Eschenroeder 1981, DOI 1987a). The Barnthouse and Eschenroeder models rely in theory on sublethal effects data, which, as mentioned previously, are often lacking. In these cases, the lack of experimental data on sublethal effects is circumvented by assuming a generic relationship between lethal and sublethal effects.

2.3.2 Degree of Integration of Information Concerning Multiple Chemicals and Pathways

Potential receptors can be exposed to multiple chemicals or other stresses via multiple pathways (e.g., water, sediment, food, air). Current approaches to integrating multiple pathways and chemicals when estimating risk are related to the particular objective of the method.

Methods Used to Set Priorities. The methods used to set priorities (EPA/OWRS 1983, EPA/OPPE 1987) that were based on professional judgment did not explicitly address multiple chemicals or pathways, although these issues presumably would be considered by the individuals conducting the analysis. The Standard Evaluation Procedure for Ecological Risk (EPA/OPP 1986) is a chemical-specific method, but considers a different dominant route of exposure for different types of receptors (aquatic and terrestrial). Similarly, because the EPA/OTS 1984 method for Estimating Concern Levels was developed to screen chemicals for further testing, the analysis is conducted for single chemicals only. The RCRA Risk-Cost Analysis model (EPA/OSW 1984) was developed to rank risks associated with managing multi-chemical waste streams. The toxicity of the waste stream in this method is based on the most toxic constituent of the waste stream.

Methods Used to Develop Standards or Guidelines. Multiple pathways and chemicals are generally not considered in methods for standards development primarily because standards usually address a single chemical in a given medium. In the AWQC methodology (EPA/OWRS 1986), exposure to predators through the food chain is addressed in addition to exposure to aquatic organisms through the water. However, the two pathways are not integrated (i.e., predatory fish are not exposed to both food and water); the most protective value is chosen as the water criterion. Similarly, the NYS/DEC (1987) Fish Flesh Criteria methodology can be used to develop residue limits for single chemicals only. The Water Quality-based Permitting for Toxic Pollutants guidelines (EPA/OWRS 1987), however, recommend assessing the toxicity of whole effluents using bioassays. The Biological Criteria for fish and macroinvertebrate communities developed by Ohio EPA (1988), on the other hand, reflect aquatic community responses to multiple chemicals and other physical stresses via all routes of exposure.

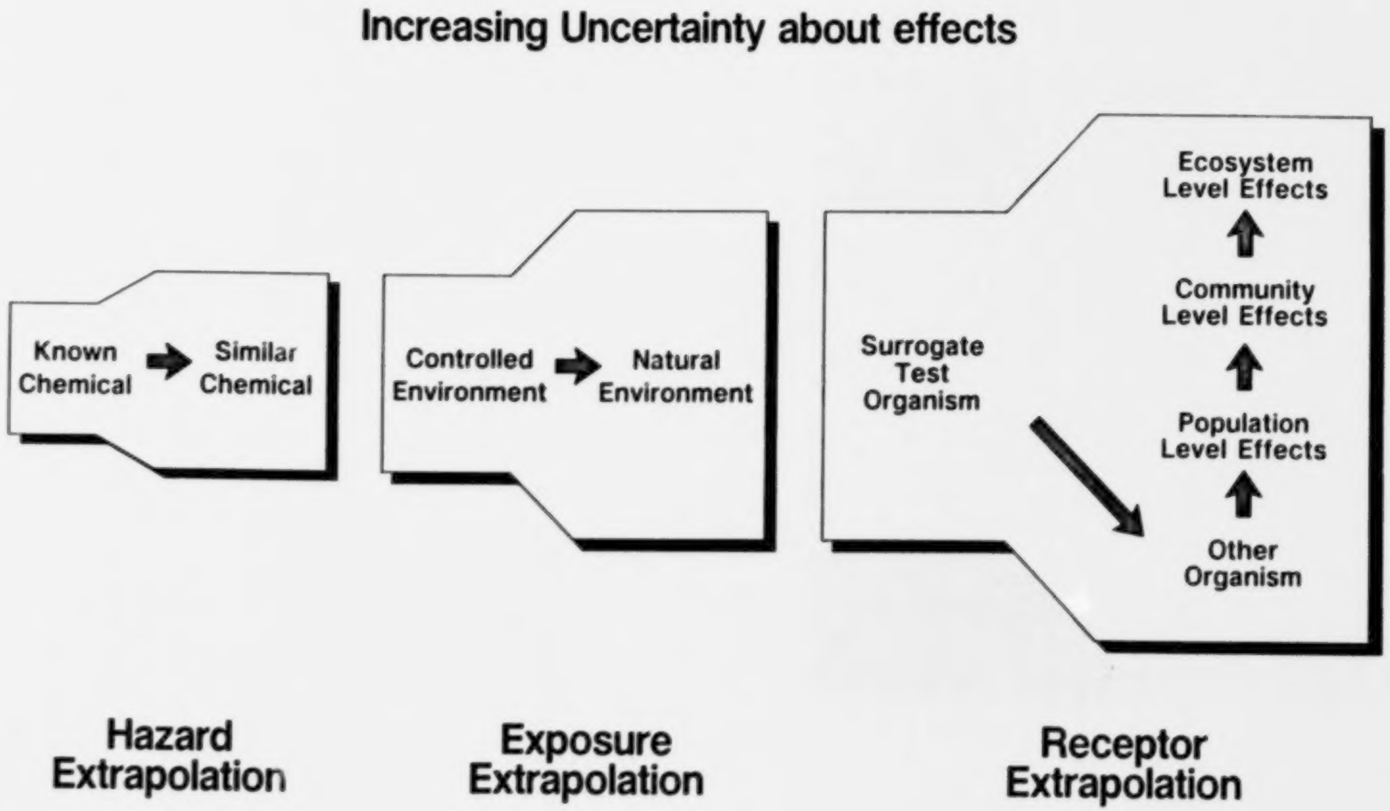
Methods Used to Assess Risk for Risk Management Decisions. Consideration of multiple chemicals and pathways are particularly important for risk assessments conducted to support risk management decisions at hazardous waste sites. At these sites, biota can be exposed to many different chemicals through several different environmental media. Only one of the methods we reviewed, however, addresses the effects of multiple chemicals (EPA/OSW 1987b). Under the hazard index approach, the ratios of estimated environmental concentrations to toxicity criteria are summed to provide an index for total risk. This approach assumes that toxicity is additive and, theoretically, is therefore appropriate for those chemicals with similar modes of action. Although the Ecosystem Uncertainty Analysis (Barnthouse et al. 1986) method does not model multiple chemicals, it does attempt to incorporate the effects of stresses in addition to the toxicant. None of methods reviewed examine multiple pathways, although the CERCLA Type A Assessment (DOI 1987a) models a different dominant route of exposure for different types of receptors.

2.3.3 Treatment of Uncertainty

There are many sources of uncertainty associated with ecological assessments. For example, each component of risk assessment (i.e., receptor, toxicity, and exposure assessment) has some uncertainty associated with it, and when these components are combined to estimate risk, new layers of uncertainty are added. Figure 5 illustrates how uncertainties associated with each component of ecological risk

FIGURE 5

UNCERTAINTY AND DATA EXTRAPOLATION


Increasing Uncertainty about effects
Known Chemical
Similar Chemical
Controlled Environment
Natural Environment
Surrogate Test Organism
Other Organism
Population Level Effects
Community Level Effects
Ecosystem Level Effects
Hazard Extrapolation
Exposure Extrapolation
Receptor Extrapolation

assessment can combine to increase the uncertainty of risk predictions. A thorough discussion of sources and treatment of uncertainty is beyond the scope of this document. In this section, we briefly discuss the way in which the methods reviewed treat uncertainty. The discussions are presented in the context of the purposes for which the various methods were developed.

Methods Used to Set Priorities. Two of the methods reviewed rely on professional judgment to set priorities (EPA/OPPE 1986, EPA/OWRS 1983). These methods do not treat uncertainty explicitly. The other methods for establishing priorities (EPA/OPP 1986, EPA/OTS 1984, EPA/OSW 1984) address uncertainty through the use of "application" or "assessment" factors. The assessment factors are used to derive an environmental concentration level which, if equaled or exceeded, is likely to elicit an adverse ecological effect. Assessment factors are based on the adequacy of available data; chemicals with limited toxicity data are assigned more conservative application factors. EPA/OTS (1984) has used the assessment factor approach extensively and has expended considerable effort in estimating appropriate factors for different sources of uncertainty. In addition, EPA/OTS (1984) uses quantitative structure activity relationships (QSAR), when appropriate, to extrapolate from tested chemicals to untested chemicals. The RCRA Risk-Cost Analysis project (EPA/OSW 1984) uses safety factors to account for the quality of data used to determine the ecosystem threshold concentration. A safety factor is similar to an application factor, except that the safety factor is intended to provide an estimate of the boundary between a no effect concentration and an effect concentration.

Methods Used to Develop Standards or Guidelines. A major source of uncertainty for methods used to develop standards or guidelines is in the definition of a reference toxicity value. There are many sources of uncertainty associated with the use of experimentally-derived reference toxicity values. Some of the largest sources of uncertainty are associated with extrapolations of data from a studied chemical, species, or time frame to unstudied chemicals, different species or communities or ecosystems, or longer time frames. In addition, there are uncertainties associated with the extrapolation of responses in laboratory species to responses of receptors in the field. There are also uncertainties associated with the statistical methods used to derive toxicity values.

In the methods we reviewed, the reference toxicity values used to develop standards or guidelines were derived from experiments designed to test a hypothesis (e.g., define a no-effect level, chronic values in EPA/OWRS 1986) or derived from exposure-response data (EPA/OAR 1986, acute values in EPA/OWRS 1986). Each of these approaches has uncertainties associated with it. The size of the experimental error depends in part on the total sample size used to derive the value. Because the total sample size needed to construct an exposure-response curve is usually larger than that used in hypothesis testing, the error should be smaller for a toxicity value derived from exposure-response data. For this reason, when they are available, reference toxicity values derived from exposure-response data are preferable to values derived from hypothesis testing.

Another common source of uncertainty is associated with deriving reference toxicity values for chemicals that have not been tested extensively. To avoid the uncertainty associated with taxonomic variation, EPA/OWRS (1986) does not develop AWQC unless minimum data requirements for taxonomic breadth are met. However, as in the methods used to set priorities, the most common treatment of uncertainty is to apply generic assessment or safety factors to a toxicity value. This approach is used to extrapolate from acute data to chronic no- or lowest-observed-effect levels (EPA/OWRS 1986), from studied species to unstudied ones, and from the effects seen in the laboratory to those expected in the field (EPA/OTS 1984).

In the case of extrapolation from acute to chronic effects, Barnthouse et al. (1982, 1986) recommends quantifying uncertainty more rigorously, through a statistical analysis of the extrapolation error. For example, under this approach, uncertainty of the extrapolation between acute (LC_{50}) and chronic (MATC) toxicity data is determined by regression of the two values for many species. The error estimate is then defined by the variance associated with the MATC-LC50 regression.

Methods Used to Assess Risk for Risk Management Decisions. In the methods that quantify risk, uncertainty arises not only in conjunction with toxicity values, but also in parameters and models used to estimate exposure and in the method used to integrate exposure and toxicity information into an estimate of risk.

Several techniques have been employed to address uncertainty in exposure estimates. DOI's (1987a) CERCLA Type A Assessment uses only one point (the mean) to represent the value of each environmental parameter. EPA/OSW (1987b) uses two values to represent a parameter: the average and the plausible worst case (e.g., upper 95th percentile). EPA/OAR (1986) used statistical confidence limits to bound long-term ozone concentrations based on confidence limits of the original (short-term) field measurements and the unexplained variation in the model regression used to predict long-term concentrations.

For reasonably complex models, a strict analytic accounting of each source of uncertainty becomes extremely labor-intensive. Therefore, more complex models (e.g. Onishi et al. 1982, 1985; Barnthouse, 1982, 1986) do not attempt to define statistical confidence limits analytically but address uncertainty using a variety of techniques. These techniques include the use of probability distributions as input variables (Onishi et al. 1982, 1985), Monte Carlo simulations (e.g., randomly combining variables chosen from several distributions; Barnthouse 1982, 1986), sensitivity analysis, calibration, and validation. Although a rigorous discussion of these techniques is beyond the scope of this document, these techniques, as used in the methods reviewed, are discussed briefly below.

The Monte Carlo simulation technique, used by Barnthouse et al. (1986), is used to represent multiple sources of environmental uncertainty. A probability distribution is measured or estimated for each of the parameter values. For each run of the Monte Carlo simulation, a single value is selected at random for each parameter from a defined probability distribution. This procedure is iterated until a reasonably stable probability distribution (convergence) is obtained for the results. The variance of the results can then be characterized. Monte Carlo simulation is a particularly useful technique for combining multiple sources of variance if parameters are not normally distributed and if the functional form of the model is non-linear. However, Monte Carlo simulation can require a long time to obtain convergence, perhaps days or months.

For important parameters that are not well-characterized (e.g., indirect effects of toxicants), sensitivity analyses can help define a range of possibilities for the final predictions. For example, Eschenroeder et al. (1981) analyzed the effect of variation in toxicant-induced mortality rates of primary producers and feeding and respiration rates at various other trophic levels on the predictions of biomass reduction at each trophic level. A sensitivity analysis has also been performed on the surface water component of Onishi et al.'s (1982, 1985) Chemical Migration Risk Assessment methodology.

The techniques discussed above help to define the uncertainty associated with a model's predictions. Other techniques help to reduce model uncertainty by increasing accuracy and precision. Validation consists of assessing the accuracy of the model by comparing model inputs and predictions with field data. Once model accuracy is defined, calibration of the model or submodels with field data can improve model accuracy. During calibration, parameter values are varied until a close match is obtained between the model predictions and the field measurements. The Ecosystem Uncertainty Analysis (Barnthouse et al. 1986) has been partially calibrated using experimental ponds, although the model itself was also modified to more closely resemble the dynamics of the ponds (as described in EPA/OTS 1987). Several of the other models (e.g., EPA/OAR 1987, Eschenroeder et al. 1981) could be calibrated using field or historical data. For example, the relationships between bioaccumulation of chemicals and octanol/water partitioning coefficients used in Eschenroeder et al. (1981) could be validated using measured chemical concentrations in tissues of animals at various trophic levels.

3.0 CONCLUSIONS AND RECOMMENDATIONS

3.1 CONCLUSIONS

Comparison of the 20 methods revealed that each method addresses one or more of the components of probabilistic risk assessment and that the scope and endpoints under consideration vary considerably. Some methods were designed primarily to aid in the setting of priorities (EPA/OSW 1987a, EPA/OPPE 1987), others to support the development of criteria and standards (EPA/OWRS 1986, EPA/OAR 1986, EPA/OTS 1984), and most of the others to provide input to risk management decisions (Eschenroeder et al. 1980, Barnthouse et al. 1986). Nonetheless, a few general conclusions can be drawn from this review:

- Methods can be grouped as qualitative or quantitative approaches; quantitative methods can be further grouped into quotient (ratio) methods or exposure-response (continuous) methods.

    - While qualitative methods cannot be used to develop standards or to quantify risk, they can be very effective as screening or ranking tools to set priorities.

    - The quotient method (yielding dichotomous predictions) appropriately addresses legislative mandates to identify "safe" levels of chemicals.

    - Exposure-response methods (yielding continuous predictions) may be more useful for risk management decisions when it is important to know the degree of damage anticipated with a specified degree of exposure.

- Methods that address changes at the community or ecosystem level can be grouped into "top-down" approaches or "bottom-up" approaches.

    - There is considerable uncertainty associated with inferring community- and ecosystem-level effects from laboratory bioassays (bottom-up approaches). Predictive tools for combining density-dependent population regulation and density-independent processes (e.g., responses to toxic chemicals) are not yet available.

    - There is also uncertainty associated with addressing ecosystem-level effects directly (top-down approaches). Exposure-response data using community- or ecosystem-level endpoints (e.g., species diversity and abundance) are extremely limited. Because of the limited data, these methods have generally been qualitative, and have been developed to help set priorities, or to document existing impacts.

  - Both types of approaches are limited in that there is no accepted definition of "ecosystem health," although characterization of appropriate reference environments might serve as an appropriate surrogate definition.

- As models become more complex and representative of real-world processes, other difficulties arise.

  - The more complex the model, the more difficult it becomes to propagate sources of error throughout an analysis. Other techniques must be applied including validation, calibration, and sensitivity analyses.

  - The more realistic the model, the less likely it is that adequate toxicological data are available. Currently, the most realistic models require estimates for biological parameters for which few supportive data exist. In particular, these data include sublethal responses to toxicants and the interactions between stressors (e.g., toxicant and temperature tolerance).

3.2 RECOMMENDATIONS

Based on this review, we recommend the following:

- Government-sponsored ecological damage assessments and monitoring efforts should be coordinated to provide usable data for ecological exposure-response modeling and exposure assessment. Points for coordination include:

  - Prescribing chemical and physical data collection (e.g., sampling protocol for contaminants in different media, including biological samples);

  - Prescribing biological data collection (e.g., species diversity, nutrient flux, indicator species, time course of response and recovery);

  - Standardizing and coordinating compilation of damage assessments;

  - Comparison of monitoring data with predictions of ecological changes that might have been made prior to the initiation of monitoring (i.e., to verify or to refute specific modeling efforts based on subsequent observations);

  - Use of monitoring data to rigorously define "healthy" ecosystems for different geographic regions of the country;

  - Sponsoring data analysis for extraction of general ecological and toxicological principles.

- Further laboratory- and field-based research is needed on several issues:
  - Interactions between stressors in animal laboratory toxicity testing;
  - Toxicant effects on sublethal endpoints such as respiration, feeding rates, susceptibility to disease, and decreased tolerance of other stressors;
  - Defining the risks associated with multiple chemical stresses or multichemical waste systems. The reliability of three approaches to this problem could be compared: (1) selecting the single most toxic constituent to represent the mixture, (2) hazard index (EPA/OSW 1987b), and (3) bioassays on the mixtures;
  - Developing models that combine both density-dependent population interactions and density-independent processes (e.g., responses to environmental contamination) in a useful predictive tool.
- Future development of ecological risk assessment methods should address several needs:
  - Increased emphasis should be placed on statistical treatment of uncertainty;
  - When practicable, emphasis should be placed on exposure-response evaluation with less emphasis on identifying "no-effect-levels" based on hypothesis testing;
  - Most ecological assessments deal primarily with direct acute effects; increased emphasis on indirect and chronic effects is needed, especially for non-point sources of contamination;
  - There is a need to identify indicators of ecosystem health and to focus on ecosystem resilience and recovery in order to define what constitutes an acceptable level of effect and to focus ecosystem modeling efforts and environmental monitoring efforts most effectively;
  - Data requirements continue to pose a problem for all but the most simple methods. To improve the utility of models that predict community-level and ecosystem-level effects, additional emphasis should be placed on the role of microcosm studies in supplying input data and in calibrating model outputs.
  - Endpoints should be chosen based on ecological, societal, and regulatory significance, as well as practicality.

- There is a need for ecosystem-level modeling efforts and more emphasis on quantitative probability-based ecological risk assessment methodologies.

GLOSSARY

The following definitions were compiled primarily from these sources: Rand and Petrocelli (1985), Krebs (1978), Odum (1971), Whittaker (1975), Webster's New Collegiate Dictionary, and the McGraw-Hill Dictionary of Life Sciences.

Anadromous: Organisms that ascend rivers from the sea to spawn or to breed.

Assessment factor: A factor that is used to derive an environmental concentration level from a specified toxicity benchmark (e.g., LC_{50}), which if equaled or exceeded is likely to cause an adverse ecological effect.

Benthos: Organisms that live on or in the bottom of bodies of water.

Bioaccumulation: The net uptake of chemicals by organisms directly from water or through consumption of food containing the chemicals.

Bioconcentration: The net uptake of chemicals by aquatic organisms from water.

Biomagnification: The net increase in chemicals in organisms at successively higher trophic levels as a consequence of ingesting contaminated organisms at lower trophic levels.

Calibration: The adjustment of model parameter values using field data.

Community: An assemblage of populations of plants, animals, bacteria, and fungi that live in an environment and interact with one another, forming a distinctive living system with its own composition, structure, environmental relations, development, and function.

Copepod: Any of a large class of microscopic freshwater and marine crustacea; also, one of the most abundant types of animal in marine zooplankton.

Demersal: Living at or near the bottom of the sea.

Density dependence: A density-dependent effect alters the birth rate or the death rate of a population as a function of the density of the population. Examples of factors that can have density-dependent effects include competition among members of the population, rates of attack by parasites and predators, and emigration.

Deterministic: A unique output or result produced by a specified input (stochastic or random selection of parameters from probability distributions are not incorporated).

Diel: A 24-hour period, usually including the day and following night.

EC50: Median effective concentration. The concentration of material in water that is estimated to be effective in producing some sublethal response in 50% of test organisms. Often used in reference to immobilization of invertebrates or reduced growth of algae.

Ecological damage assessment: A subcategory of ecological impact assessment that measures effects that have already occurred in an ecosystem or any part of an ecosystem as the result of a perturbation. As the phrase is used in this report, damage assessments can measure injury (i.e., adverse effects that may not have economic consequences) as well as damage (i.e., adverse effects that can be measured in economic terms). Measurements of damages that have already occurred can be used as input into probabilistic ecological risk assessments.

Ecological impact assessment: A subcategory of environmental impact assessment that addresses impacts on non-human biota by documenting and/or estimating the occurrence of impacts within an ecosystem or any part of an ecosystem, and the consequences of the occurrence.

Ecological risk assessment: A subcategory of ecological impact assessment that (a) predicts the probability of adverse effects occurring in an ecosystem or any part of any ecosystem as a result of a perturbation and (b) relates the magnitude of the impact to the perturbation.

Ecological risk management analysis: A decision-making process that considers political, social, economic, and engineering information in conjunction with risk-related information to select an appropriate regulatory response to a potential ecological problem.

EEC: Estimated environmental concentration.

Environmental impact assessment: A broad field that includes all activities that attempt to analyze and evaluate the effects of human action on natural and anthropogenic environments (after Suter _et al_. 1987).

Ecosystem: The biotic community and its environment which, together, function as a system of complementary relationships, with the transfer and circulation of energy and matter.

Environmental impact assessment: A broad field that includes all activities that attempt to analyze and evaluate the effects of human action on natural and anthropogenic environments (after Suter _et al_. 1987).

Environmental Impact Statement (EIS): An assessment of the impacts of a specific Federal action as required by the National Environmental Policy Act (NEPA). Although an EIS may use ecological risk assessment as a tool for comparing alternatives, an EIS is required only to provide a "full and fair discussion of significant environmental impacts".

Environmental risk assessment: A procedure that predicts (a) the possibility of adverse effects occurring to human health or the environment and (b) the consequences of the adverse effects (after NRC 1975).

Fecundity: Potential capability of an organism to produce viable offspring.

GMATC: The point estimate of the Maximum Acceptable Toxicant Concentration (MATC) calculated as the geometric mean of the no-effect level (NOEL) and the low-effect level (LOEL) taken from life-cycle or partial life-cycle toxicity tests.

Hardness: The concentration of all divalent metallic cations, except those of the alkali metal, present in water. In general, hardness is a measure of the concentration of calcium and magnesium ions in water and is frequently expressed as mg/l calcium carbonate equivalent.

Hazard assessment: A component of risk assessment that consists of the review and evaluation of toxicological data to identify the nature of the hazards associated with a chemical, and to quantify the relationship between dose and response.

Ichthyoplankton: The drifting eggs and larvae of many species of fish.

LC_{50}: Median lethal concentration. The concentration of substance in water that is associated with the death of 50% of the organisms in a laboratory bioassay. This notation is also used to describe other proportions; for instance LC_{10}, LC_{25}, and LC_1 refer to the concentrations estimated to kill 10%, 25% and 1% of the test organisms, respectively.

LOEL: Lowest observed effect level. The lowest level or concentration of a material used in a toxicity test that produces a statistically significant adverse effect on the exposed population of test organisms as compared with the controls.

MATC: The toxic chemical threshold concentration lying in a range bounded at the lower end by the highest tested concentration having no effect (NOEL) and at the higher end by the lowest tested concentration having a significant toxic effect (LOEL) in a life cycle (full chronic) or partial life cycle (partial chronic) test.

Microcosm: A laboratory simulation of a portion of an ecosystem (e.g., a terrarium).

Mesocosm: A composite physical and biological model of an ecosystem, intermediate in scale between a microcosm and a macrocosm, with a level of organization as high as the natural world (e.g., ponds).

Macrocosm: A composite physical and biological model of an ecosystem, large in scale, with a level of organization as high as the natural world (e.g., an experimental watershed including terrestrial and aquatic ecosystems).

Macroinvertebrates: Invertebrate species that are sufficiently large to be handled without the aid of a microscope.

Monte Carlo simulation: An iterative modeling technique where parameter values are drawn at random from defined probability distributions, a solution defined, and the process repeated until a stable distribution of solutions results.

NOEL: No observed effect level. The highest concentration in a toxicity test that has no statistically significant adverse effect on the exposed population of test organisms as compared with the controls.

Niche: Role or "profession" of an organism in the environment; its activities and relationships in the community.

Piscivorous: Fish-eating.

Phytoplankton: Drifting aquatic plants, usually uni-cellular.

Phytotoxic: Toxic to plants.

Planktivorous: Eats drifting aquatic organisms.

Plankton: Microscopic or small macroscopic plants and animals which live freely in surface water and which, because of their limited powers of locomotion, drift with the water currents.

Population: A potentially interbreeding group of individuals of a single species.

Primary productivity: The rate at which radiant energy is stored by photosynthetic and chemosynthetic activity of producer organisms (chiefly green plants) in the form of organic substances.

QSAR: Quantitative structure activity relationship: a method of estimating unmeasured physical and toxicological properties for a chemical on the basis of chemical structure, functional groups, and similarity to known chemicals.

Receptor: The entity (e.g., organism, population, community, ecosystem) that might be adversely affected by contact with or exposure to a substance of concern.

Resilience: The ability of a system to recover from perturbations.

Resistance: The ability of a system to absorb an impact without significant change from normal fluctuations.

Risk management: The process of weighing policy alternatives and selecting the most appropriate regulatory action based on the results of risk assessment.

Secondary productivity: Rate of energy storage by heterotrophic organisms (i.e., rate of energy storage at consumer levels - herbivores, carnivores, or detritus feeders).

Species: A group of closely related, morphologically similar individuals which actually or potentially interbreed.

Stochastic: A process involving a random variable.

Stratosphere: The upper portion of the atmosphere, in which temperature varies very little with changing altitude and clouds are rare.

Trophic level: Functional classification of organisms in a community according to feeding relationships; the first trophic level includes green plants; the second trophic level includes herbivores; and so on.

Validation: The testing of a model against reality.

Zooplankton: Drifting aquatic animals.

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APPENDIX A

FRAMEWORK FOR REVIEW OF LEGAL MANDATES AND ECOLOGICAL ASSESSMENT METHODOLOGIES

APPENDIX A

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INTRODUCTION

To ensure consistency among our reviews, we developed a series of frameworks for reviewing legal mandates and ecological assessment methodologies. We describe these frameworks in this appendix. First we discuss our standardized approach for reviewing legal mandates. This is followed by a discussion of our framework for reviewing the technical aspects of the ecological assessment methodologies, and then our framework for assessing operational resource requirements.

1.0 FRAMEWORK FOR REVIEWING LEGAL MANDATES

Legislative mandates and executive order directives were reviewed to determine the degree to which they may require ecological risk assessment. For example, a statute or directive either (1) explicitly requires risk assessment; (2) requires consideration of ecological effects; (3) may require, generally or implicitly, consideration of ecological impacts; or (4) does not require any ecological impact evaluation. Our framework for reviewing legal mandates is shown in Table A-1.

2.0 FRAMEWORK FOR REVIEWING TECHNICAL ASPECTS OF ECOLOGICAL ASSESSMENT METHODOLOGIES

The technical review of the ecological assessment methodologies was structured around the four major components of the ecological risk assessment process: (1) receptor characterization, (2) hazard assessment, (3) exposure assessment, (4) risk characterization. Although the four components are discussed separately, it should be noted that they are integrally connected. For example, the receptor characterization influences what toxicological data are used and what exposure pathways are considered. Similarly, the limitations of the model or method of risk characterization will determine what receptors can be adequately evaluated.

2.1 RECEPTOR CHARACTERIZATION

Receptor characterization is important in ecological assessments because it defines the scope of the assessment as well as some of the inputs to hazard and exposure assessment. Table A-2 lists the five general considerations used for the review of receptor characterization: type (e.g., aquatic, terrestrial), level (i.e., individual through ecosystem), specificity (e.g., generic, biome, or location specific), temporal characterization (e.g., seasonal, life-cycle considerations), and niche (or life-habit) characterization. Each of these is an important component of overall receptor characterization.

It is doubtful that any ecological impact assessment methodology currently includes information on all of these characteristics. For example, complete characterization of potential receptors would consider all types and all levels, as well as the temporal and life-habit characteristics of the receptors. Although few methodologies characterize receptors so completely, these characteristics are presented to compare currently used methodologies with future advances in methodological approaches.

2.2 HAZARD ASSESSMENT

The hazard assessment component of an ecological assessment identifies the chemical-specific toxicological effects for each receptor of concern. As shown in Table A-3, hazard assessments may be based on toxicological data for different levels of receptor characterization (e.g., individuals,

TABLE A-1

FRAMEWORK FOR REVIEWING LEGAL MANDATES

1.0 Legislative Mandate
    1.1 Requires ecological risk assessment
    1.2 Requires consideration of ecological impacts
    1.3 May require consideration of ecological impacts
    1.4 Not relevant to ecological impacts

2.0 Executive Order Directive
    2.1 Requires ecological risk assessment
    2.2 Requires consideration of ecological impacts
    2.3 May require consideration of ecological impacts
    2.4 Not relevant to ecological impacts

TABLE A-2

FRAMEWORK FOR REVIEWING RECEPTOR CHARACTERIZATION

1. Type
    - 1.1 Aquatic
    - 1.2 Terrestrial

2. Level
    - 2.1 Individual (e.g., endangered species)
    - 2.2 Population (e.g., game species, keystone species)
    - 2.3 Biotic community (e.g., one guild, food web)
    - 2.4 Ecosystem

3. Receptor Specificity
    - 3.1 Generic (e.g., generic indicator species)
    - 3.2 Site-specific (e.g., Chesapeake Bay)

4. Temporal Characterization
    - 4.1 Seasonal (e.g., breeding, migration)
    - 4.2 Life cycle

5. Niche (life habit) Characterization

TABLE A-3

FRAMEWORK FOR REVIEWING HAZARD ASSESSMENT

---

1. Individual/Population Receptors
    - 1.1 Acute criteria (i.e., short duration exposure; e.g., LC_{50})
    - 1.2 Chronic criteria (i.e., longer term exposure; e.g., stunted growth)
    - 1.3 Mechanism of action
    - 1.4 Exposure-response

2. Community/Ecosystem Endpoints
    - 2.1 Criteria
    - 2.2 Exposure-response

3. Toxicity Modifying Factors
    - 3.1 Abiotic conditions/stresses
    - 3.2 Biotic stresses (e.g., competition)
    - 3.3 Behavioral changes
    - 3.4 Bioconcentration

4. Treatment of Uncertainty
    - 4.1 Generic safety factors
    - 4.2 Ranges
    - 4.3 Statistical extrapolation

5. Hazard Value Derivation
    - 5.1 Apply relative weights to effects
    - 5.2 Choose most sensitive effect

---

populations, communities) and may consider a variety of receptor-specific toxicity values (e.g., acute, chronic, dose-response), as well as the general factors which influence the probability (e.g., toxicity modifying factors) or interpretation (e.g., hazard value derivation, treatment of uncertainty) of a toxic response. Ecological assessment methodologies may be characterized and differentiated to a large degree based on variations in the approaches for hazard assessment.

Complete evaluation of potential toxicological hazards should include evaluation of lethal and sublethal endpoints at the individual, population, community, and ecosystem receptors. Historically, most toxicological data used in environmental assessments have been measurements of laboratory population responses, such as LC_{50} and MATC values. The majority of current approaches continue with this emphasis. Community-level toxicity tests (e.g., effects on community diversity) have not been standardized enough to be widely used in current methods.

With regard to toxicity values, acute and chronic criteria, mechanisms of action, and dose-response information have been used or may be used in ecological hazard assessments and are considered to represent currently feasible approaches. Similarly, some assessment methodologies consider toxicity modifying factors (e.g., abiotic and biotic stresses) and incorporate estimates of uncertainty.

2.3 EXPOSURE ASSESSMENT

An exposure assessment estimates the chemical-specific concentrations to which receptors are exposed. As shown in Table A-4, exposure assessments can encompass multiple exposure pathways, concentration variations, toxicity modifying factors, and uncertainties surrounding the exposure estimates.

2.4 RISK CHARACTERIZATION

The final stage in the ecological assessment process is the integration of the information derived during receptor characterization, hazard assessment, and exposure assessment to generate an estimate of impact or risk. Risk characterization varies with respect to the type of approach/model used to estimate risk (e.g., qualitative, quantitative); the degree of integration of multiple stressors or pathways of exposure, and the applicability of the approach/model to a variety of situations. In addition, models used for risk characterization vary in the treatment of uncertainty and in the degree to which they are validated, calibrated, verifiable, and sensitive. Each of these characteristics is listed in Table A-5.

TABLE A-4

FRAMEWORK FOR REVIEWING EXPOSURE ASSESSMENT

1. Exposure Pathways
    1.1 Soil
    1.2 Air
    1.3 Water
    1.4 Sediment
    1.5 Food

2. Concentration Estimation Methods
    2.1 Spatial variation within/between media (e.g., concentration is a continuous or step function of distance from source)
    2.2 Temporal variation within/between media (e.g., steady state or time varying contaminant release)
    2.3 Toxicokinetics (e.g., bioconcentration of substance)

3. Characterization of Toxicity Modifying Factors (e.g., D.O., pH, temperature)

4. Treatment of Uncertainty
    4.1 Deterministic model
    4.2 Average (i.e., typical case) or maximum (i.e., worst case) estimates
    4.3 Probability distribution of concentrations

TABLE A-5

FRAMEWORK FOR REVIEWING RISK CHARACTERIZATION

---

1. Type of Approach
   1.1 Qualitative
   1.2 Quantitative

2. Degree of Integration
   2.1 Contaminants
      2.1.1 Single (or indicator) chemical
      2.1.2 Multiple chemicals

   2.2 Route of Exposure
      2.2.1 Single route or dominant route
      2.2.2 Multiple routes

   2.3 Contributions of Other Stresses

3. Applicability of Model/Approach
   3.1 Limited (e.g., specific to a particular situation or locality)
   3.2 Broadly applicable/flexible

4. Treatment of Uncertainty
   4.1 Reflects uncertainty in measurements
   4.2 Reflects biotic and environmental variability
   4.3 Estimates probability distribution of effects

5. Can Be Validated
   5.1 Has been partially field tested
   5.2 Has been completely field tested
   5.3 Can be field tested

6. Can Be Calibrated (i.e., adjusted to reflect the environmental situation at hand)

7. Can be Evaluated for Sensitivity (i.e., changes in output of model accurately reflect changes of inputs)

8. Is Verifiable
   8.1 Model code/behavior accurately represents algorithm
   8.2 Algorithms are scientifically reasonable and/or field verified

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3.0 FRAMEWORK FOR REVIEWING OPERATIONAL RESOURCE REQUIREMENTS

Our review of operational resource concerns addresses the issue that while some aspects of methodologies do not affect the scientific approaches of the model, they may influence the degree to which the model is applied. For example, a complex computer simulation model may be extremely expensive to run, and this may limit its use. In addition, complex models may require data that are not available for a wide range of chemicals or organisms. The primary operational resource concerns considered are data availability, cost, and the level of effort and skill required to implement the ecological assessment. The framework for reviewing operational resource requirements is given in Table A-6.

TABLE A-6

FRAMEWORK FOR REVIEWING OPERATIONAL RESOURCE REQUIREMENTS

1. Data Availability
    - 1.1 Available (i.e., most receptors, most chemicals)
    - 1.2 Limited availability (i.e., few receptors, few chemicals)
    - 1.3 Can be extrapolated using similar species/populations or chemicals

2. Cost/Level of Effort
    - 2.1 High
    - 2.2 Medium
    - 2.3 Low

3. Level of Skill Required
    - 3.1 High
    - 3.2 Low

APPENDIX B

REVIEW OF LEGAL MANDATES FOR ECOLOGICAL RISK ASSESSMENTS

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2.7 Wild and Scenic Rivers Act B-20

INTRODUCTION AND MAJOR CONCLUSIONS

This appendix presents a review of legal mandates for ecological risk assessment. The review includes 15 statutes and directives, eight of which are administered by EPA, with the remaining seven administered by other agencies within the Federal government. We also examined the legislative histories for several statutes in order to interpret the intent of specific provisions within the legislation. It should be noted that a review of regulations promulgated in the Federal Register was outside the scope of this project. Hence, specific regulations for ecological risk assessment such as those promulgated under FIFRA (e.g., 40 CFR 162.11) are not addressed in this document. The statutes and directives administered by EPA are presented first, followed by the legislation administered by other Federal agencies.

Protecting the environment or various components of the environment is a clear common goal or objective of each of the 15 statutes and directives reviewed. The statutes and mandates do not describe specifically how protection of the environment is to be accomplished. Nevertheless, given the goals and objectives of the statutes and directives, it is arguable that all may require some consideration of ecological impacts even though none explicitly requires formal ecological risk assessment. However, all of them allow, and some appear to actually encourage, conducting an ecological risk assessment.

Of the eight statutes administered by EPA, four appear to require consideration of ecological impacts in support of standards, limitations, and regulations development. Ecological impact considerations are also required to support waivers, exemptions, etc., from regulatory standards, limitations, and requirements, and to support research activities related to the impacts of regulations or in support of future regulations. These statutes specify the activities or biota for which a consideration of environmental impact is required (e.g., propagation of shellfish, fish, etc.). The remainder of the statutes administered by EPA may require consideration of ecological impact and would allow the use of administrative discretion to require an assessment to ensure protection of the environment. In general, these statutes and directives do not specify activities and biota for which an assessment must be provided or which methods must be used in performing the assessment.

The Clean Air Act (CAA), Clean Water Act (CWA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), the Marine Protection, Research, and Sanctuaries Act (MPRSA), the Endangered Species Act (ESA), the National Environmental Policy Act (NEPA), the Wild and Scenic Rivers Act, and Executive Order 11990 (Protection of Wetlands) require consideration of ecological impacts. Of these statutes, the CAA, CWA, FIFRA, and MPRSA are administered by EPA. Each of these statutes contains sections for which consideration of ecological impacts is required and sections which seem to encourage performing formal ecological risk assessments. For example, to obtain a modification of secondary treatment requirements under Section 301(h) of the CWA, a municipality must first demonstrate that the modification will not result in interference with maintenance of water quality that ensures the "protection and propagation of a balanced, indigenous population of shellfish, fish, and wildlife." Under Section 102(a) of MPRSA, prior to issuing a permit for ocean dumping, the Administrator must consider the effects on marine ecosystems, including the transfer, concentration, and dispersion of waste, the potential changes in marine ecosystem diversity, productivity, and stability, and marine species and community population dynamics.

The Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the Resource Conservation and Recovery Act (RCRA), the Toxic Substances Control Act (TSCA), the Safe Drinking Water Act (SDWA), the Coastal Zone Management Act of 1972 (CZMA), the Fish and Wildlife Coordination Act, and Executive Order 11988 (Floodplain Management) may require consideration of ecological impacts. Of these, CERCLA, RCRA, SDWA, and TSCA are administered by EPA. Sections within each of these statutes require that environmental impacts be considered. Implicitly, this includes ecological impacts. In addition, each statute provides sufficient administrative discretion and flexibility to require this consideration. For example, authorization for the land disposal of hazardous wastes under RCRA Sections 3004(d) and (e) can be granted only for disposal methods that are shown to be protective of human health and the environment.

1.0 STATUTES AND DIRECTIVES ADMINISTERED BY EPA

Table B-1 provides a summary of ecological assessment requirements of eight statutes and directives administered by EPA. A brief description of the requirements for each statute and directive is provided below.

1.1 Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)

The objective of CERCLA (including amendments made under the Superfund Amendments and Reauthorization Act of 1986) is to establish a National program for responding to releases of hazardous substances into the environment. CERCLA establishes the process for determining appropriate remedial actions at Superfund sites; remedial actions selected are required to be cost-effective and adequate to protect public health.

Several sections of CERCLA require that environmental impact assessments be performed for certain activities, although neither the Act nor its legislative history specifies methods or techniques for the assessments. The environment is defined to include natural resources that are under the exclusive management authority of the U.S. Natural resources are further defined under CERCLA to include land, fish, wildlife biota, air, water, ground water, drinking water supplies, and other resources. Therefore, although there is not an explicit requirement for an ecological assessment, the definitions provided could be interpreted to require one.

Under the National Contingency Plan, Section 105 of CERCLA, several provisions require the consideration of the threat of, and subsequent hazards related to, the release of hazardous substances to the environment. Section 105(a)(8)(A) requires criteria to be established for determining priorities among releases or threatened releases of hazardous substances for purposes of taking removal actions. These criteria must be based upon "the relative risk or danger to... the environment, (including) the potential for destruction of sensitive ecosystems." Under Section 105(d) of CERCLA, the President can be petitioned to conduct a preliminary assessment of a release or threatened release of a hazardous substance. This preliminary assessment must consider the hazards associated with a release or threatened release posed to public health and the environment. To add facilities to the National Priorities List (NPL) pursuant to Section 105(g) of CERCLA, the potential exposure and hazard of substances to human health and the environment must be considered. Section 121 (added pursuant to the 1986 amendments) of CERCLA defines how to assess alternative remedial actions and the degree of cleanup required for Superfund sites. This assessment must account in part for the potential threat to human health and the environment. Section 301(c) of CERCLA specifies that two types of procedures be developed to assess damages "for injury to, destruction of, or loss of natural resources resulting from a release of oil or a hazardous substance." The first type of procedure must include minimal field observation. The second type must include protocols for assessing damage on a case-by-case basis, including identification of the best available procedures to determine such damages considering factors such as replacement value, use value, and ability of ecosystem or resource to recover.

TABLE B-1

SUMMARY OF THE LEGAL MANDATE FOR ECOLOGICAL ASSESSMENT (EPA)

Legislation	Applicable Section(s)	Activities For Which Ecological Assessment Required/Recommended	Citation Summary
CERCLA (including SARA)	105(a)(8)(A)	Revision of the National Contingency Plan	Required in part to develop criteria to develop priorities for the national hazardous substance response plan, based upon relative risk or danger to the environment including the potential for destruction of sensitive ecosystems.
	105(d)	Petitioning to conduct a preliminary assessment resulting from the release or threatened release of a hazardous substance	Preliminary assessment must be conducted of the hazards to public health and the environment associated with such release or threatened release.
	105(g)	Adding facilities to the National Priorities List	Need to consider quantity, toxicity, and concentration of hazardous substances, exposure or potential exposure to environment, and degree of hazard to the environment.
	121(b) & (d)	Assessment of alternative remedial actions and degree of cleanup required	Must take into account, in part: 1) The persistence, toxicity, mobility, and propensity to bioaccumulate of such hazardous substances and their constituents, and 2) The potential threat to human health and the environment associated with excavation, transportation, redisposal, or containment.
	301(c)	Development of procedures to assess damage, destruction, or loss of Natural Resource due to release of oil or hazardous substances	Required to develop two types of procedures: 1) Simplified assessments requiring minimal field observation; and 2) Alternative methods for conducting case-by-case assessments using best available procedures and accounting for factors such as ability of ecosystem to recover, etc.
	311(a)	Conducting research on hazardous substances	Research may include evaluation of basic biological, chemical, and physical methods to reduce the amount and toxicity of hazardous substances

TABLE B-1 (Continued)

SUMMARY OF THE LEGAL MANDATE FOR ECOLOGICAL ASSESSMENT (EPA)

Legislation	Applicable Section(s)	Activities For Which Ecological Assessment Required/Recommended	Citation Summary
Clean Air Act	154(c)	Studies by National Science Foundation	Encouraged to support ongoing stratospheric research to assess effects of changes in the ozone layer upon living organisms and ecosystems.
	154(d)	Studies by Secretary of Agriculture	Encouraged to assess effects upon animals, crops, and other plant life of changes in the ozone layer.
	164(b)	Redesignation of areas as Class I, II, or III	Must describe and analyze environmental effects of proposed redesignation.
	165(e)	Preconstruction requirements for major emitting facilities	Require analysis of ambient air quality, climate and meteorology, terrain, soils, and vegetation.
Clean Water Act	301(g)	Request for water-quality related variances from national effluent limitations	Must show that variance will not interfere with attainment with maintenance of water quality which shall assure the protection and propagation of a balanced population of shellfish, fish, and wildlife, and will not pose unacceptable risk to the environment.
	301(h)	Request for modifying secondary treatment requirements for POTWs that discharge into marine waters	Must demonstrate that modification will not result in interference or maintenance of water quality which assures protection and propagation of a balanced population of shellfish, fish, and wildlife.
	303(c)	Development of State water quality standards including designated use(s) for receiving waters	Standards must be established taking into consideration in part their use and value for the propagation of fish and wildlife.
	304(a)	Development of Federal water quality criteria	Criteria must reflect: 1) identifiable effects on the health and welfare of plankton, fish, shellfish, wildlife, plant life, shorelines, etc.; 2) Concentration and dispersal of pollutants or their byproducts, through biological, chemical, and physical processes; and 3) effects of pollutants on biological community diversity, productivity, and stability.

TABLE B-1 (Continued)

SUMMARY OF THE LEGAL MANDATE FOR ECOLOGICAL ASSESSMENT (EPA)

Legislation	Applicable Section(s)	Activities For Which Ecological Assessment Required/Recommended	Citation Summary
Clean Water Act (cont'd)	304(a)	Development of guidance for water quality criteria	Must publish information on methods for establishing and measuring water quality criteria including biological monitoring and assessment methods.
	305(b)	Development of State water quality inventories	Requires an analysis of extent to which water quality achieves goals of the act. Further, an environmental impact analysis is required for additional actions proposed to achieve goals of act.
	307(a)	Additions to, or revision of, the list of priority pollutants	Need to account for toxicity, persistence, degradability, potential presence of affected organisms, and effect on organisms.
	311(b)	Designation of hazardous substances	Substances that are to be designated as hazardous are those which present imminent and substantial danger to fish, shellfish, wildlife, shorelines, etc.
	316(a)	Establishment of effluent limitations for thermal discharges	Must be established to assure protection and propagation of a balanced, indigenous population of shellfish, fish, and wildlife.
	320(b)	Development of estuary protection program by a management conference	Program includes research to assess the impacts of discharges on ecosystems of estuaries of concern.
	403(c)	Development and revision of Federal ocean discharge criteria	Effect on marine life must be considered in developing criteria including the transfer, concentration; and dispersal of pollutants through biological, chemical, or physical processes; changes in marine ecosystem diversity productivity, and stability; and species and community population changes.
	404(c)	Determination of effect of dredge and fill activities prior to authorization to discharge to surface waters	Must determine if discharge will have unacceptable adverse effect on shellfish beds and fishery areas (including spawning and breeding areas) and wildlife.

TABLE B-1 (Continued)

SUMMARY OF THE LEGAL MANDATE FOR ECOLOGICAL ASSESSMENT (EPA)

Legislation	Applicable Section(s)	Activities For Which Ecological Assessment Required/Recommended	Citation Summary
FIFRA	3(c)(5)	Approval of registration of pesticide.	Must determine if, when used in accordance with widespread and commonly recognized practice, pesticide will not generally cause unreasonable adverse effects on the environment.
	3(d)(1)(B)	Classification of pesticides: general use.	Must determine that pesticide, when used in accordance with directions, warnings and cautions and for uses for which it is registered, will not cause unreasonable adverse effects on the environment.
	3(d)(1)(C)	Classification of pesticides: restricted use.	Must determine that pesticide, when used in accordance with directions, warnings and cautions and for uses for which it is registered may cause, without additional regulatory restrictions, unreasonable adverse effects on the environment.
	5(d)	Experimental use permit: required studies	May specify that studies be conducted to detect whether use of pesticide may cause unreasonable adverse effects on the environment.
	20	Research and Monitoring	As necessary, Administrator required to: o monitor air, soil, water, man, plants and animals, o quantify incidental human and environmental pesticide pollution, o identify sources of contaminants and their relationship to human and environmental effects.
	25	Development of Regulations	Authority of Administrator to prescribe regulations that take into account differences in concept and usage between classes of pesticides, differences in environmental risk and the appropriate data for evaluating such risk between agricultural and nonagricultural pesticides.

TABLE B-1 (Continued)

SUMMARY OF THE LEGAL MANDATE FOR ECOLOGICAL ASSESSMENT (EPA)

Legislation	Applicable Section(s)	Activities For Which Ecological Assessment Required/Recommended	Citation Summary
MPRSA	102(a)	Permits for ocean dumping; criteria for reviewing and evaluating applications.	Must consider effect on fisheries resources, plankton, fish, shell fish, wildlife, shore lines, and beaches. Must consider effect on marine ecosystems. Must consider particularly with respect to: o transfer, concentration, and dispersion of material, o potential changes in marine ecosystem diversity, productivity, and stability, and o species and community population dynamics. Must consider persistence and permanence of the effects of the dumping.
	102(c)	Designation of sites or times for dumping, or sites and times within certain materials may not be dumped.	Designation of times or sites in order to protect critical areas is to be based upon criteria established under Section 102(a).
	104(h)	Permitting criteria for dumping of low-level radioactive waste (two-year period from date of enactment).	Dumping must be necessary to conduct research to determine whether dumping of such substance will unreasonably degrade or endanger the marine environment, or ecological systems. Dumping must be preceded by baseline studies of proposed site and surrounding environment.
	104(i)	Permit criteria for dumping radioactive waste (two years after date of enactment).	Applicant must carry out a comprehensive monitoring plan that includes fish and benthic animal sampling. Applicant must assess analysis of environmental impact on human health and welfare and marine life.
	202(a)(2)	Research on ocean dumping	Comprehensive research on ocean dumping is required to define and quantify the degradation of the marine environment and assess the health of the marine environment.

TABLE B-1 (Continued)

SUMMARY OF THE LEGAL MANDATE FOR ECOLOGICAL ASSESSMENT (EPA)

Legislation	Applicable Section(s)	Activities For Which Ecological Assessment Required/Recommended	Citation Summary
MPRSA (continued)	303(b)	Designation of national marine sanctuaries	Factors to be considered include the national resources and ecological qualities of an area, and the present and potential activities that may affect these natural resources and ecological qualities.
RCRA	1008(a)	Develop and revise suggested guidelines for solid waste management	Guidelines must provide technical and economic description of the level of performance that can be attained by available management practices that provide for protection of public health and the environment.
	3004(b)	Authorization to place hazardous wastes in salt dome formations, etc.	Placement is prohibited until the Administrator has determined that placement is protective of human health and the environment.
	3004(d) & (e)	Authorization for the land disposal of hazardous wastes	Land disposal for hazardous waste prohibited unless method is shown to be protective of human health and the environment, accounting for in part the persistence, toxicity, mobility, and propensity to bioaccumulate
	3004(g)	Land disposal prohibitions of hazardous wastes	Listed hazardous wastes may be subject to land disposal prohibitions if disposal by a given land disposal method is not protective of the public health or environment.
	3004(m)	Development of treatment standards for wastes subject to land disposal prohibitions	Standards must be developed to minimize short-term and long-term threats to human health and the environment.
	3005(j)	Study and report to Congress on existing surface impoundments subject to exemption under 3005(j)(3)	Must account for the potential threat to human health and the environment of existing surface impoundments.
	8001(a)	Research, demonstration, and training relating to hazardous waste management	In part, required to conduct studies on improvements in land disposal practices which may reduce the adverse environmental effects, particularly for earlier and existing landfills

TABLE B-1 (Continued)

SUMMARY OF THE LEGAL MANDATE FOR ECOLOGICAL ASSESSMENT (EPA)

Legislation	Applicable Section(s)	Activities For Which Ecological Assessment Required/Recommended	Citation Summary
RCRA (continued)	8002(f),(m), (n),(o),& (p)	Special waste studies	Each study must account for the potential danger to human health and the environment from specific waste management practices.
SDWA	1427(d)	Development of criteria for the identification of critical aquifer protection areas.	Environmental costs and benefits have to be considered during identification of critical aquifer protection areas.
TSCA	4(a)	Testing to develop data with respect to health and environmental effects of substances or mixtures manufactured, distributed in commerce, processed, used, or disposed of.	Required only when insufficient data exists for the substance or mixture, to determine if an unreasonable risk of injury to health and environment is present.
	4(b)	Establishment of standards for the development of test data for substances or mixtures	Standards for development of test data for substances or mixtures may be prescribed for: o Environmental effects o Chemical characteristics o Methodologies for determining effects
	5(b)	Notification and submission of test data required for manufacture of a new chemical substance or processing any chemical substance for a new use.	Test data required must show that the new substance or new use will not present an unreasonable risk of injury to health or the environment.
	5(h)	Exemption from notification requirements for test marketing purposes.	Must show that the manufacture, processing, distribution in commerce, use, and disposal of a substance will not present any unreasonable risk of injury to health or the environment.
	6(e)	Authorization to manufacture or use PCBs in a manner other than totally enclosed.	Must show that manufacture or use will not present any unreasonable risk or injury to health and the environment.
	12(a)	Substance or mixture being manufactured, processed, or distributed in commerce for export	May require testing (pursuant to Section 4 of TSCA) if unreasonable risk may be present to health and the environment.

Finally, Section 311 of CERCLA requires basic research of hazardous substances involving evaluation of methods to reduce the amount and toxicity of hazardous substances.

1.2 Clean Air Act

The purpose of the Clean Air Act is to protect and enhance the quality of the Nation's air resources through the prevention and control of air pollution. Although the primary objective of the Clean Air Act is to promote the public health and welfare, several provisions in the Act require evaluation of environment impacts. Subchapter I, Part B, Ozone Protection, encourages studies to assess effects of changes in the ozone layer upon living organisms and ecosystems. Subchapter I, Part C, Prevention of Significant Deterioration of Air Quality, requires that the criteria for reclassification of protected areas and the redesignation of preconstruction requirements for major emitting facilities include an assessment of environmental effects. The Act does not specify the methods for or the components of an environmental assessment.

1.3 Clean Water Act

The objective of the Clean Water Act (as amended by the Water Quality Act of 1987) is to restore and maintain the chemical, physical, and biological integrity of the Nation's waters. One of the National goals established by the Clean Water Act is to attain water quality that provides for the protection and propagation of fish, shellfish, and wildlife. The objective and goals of the Clean Water Act are achieved through the control of discharges of pollutants to surface waters.

The requirements for an ecological assessment under the Clean Water Act fall primarily under Title III, Standards and Enforcement, and Title IV, Permits and Licenses. Under Sections 303 and 304 of the Clean Water Act, States and EPA are required to develop standards and criteria, considering the use and value of waters, and must assure the protection and propagation of a balanced population of shellfish, fish, and wildlife. In addition, States are required under Section 305 of the Act to provide EPA with a water quality inventory. This inventory must include an analysis of the extent to which the quality of State waters provides for the protection and propagation of a balanced population of shellfish, fish, and wildlife.

Section 307(a) of the Clean Water Act requires EPA to establish a list of priority pollutants. In adding to or revising this list, EPA must account for the toxicity, persistence, and degradability of the pollutant, and the potential presence of affected organisms and the effects on these organisms. Under Section 311(b), EPA is required to designate as hazardous those substances that present imminent and substantial danger to fish, shellfish, wildlife, shorelines, etc. Effluent limitations established for thermal discharges under Section 316(a) of the Act must assure protection and propagation of a balanced, indigenous population of shellfish, fish, and wildlife. Waivers or exemptions from standards established under the Clean Water Act (e.g., 301(g) and 301(h)) may not be granted unless it is shown that the variance will not interfere with the maintenance or attainment of water quality that assures the protection and propagation of a balanced population of shellfish, fish, and wildlife.

Under Title IV, EPA is required to establish control over discharges to the Nation's waters. The criteria for discharges to oceans under Section 403(c) must consider the effects on marine life, including changes in marine ecosystem diversity, productivity, and stability. Section 404(c) of the Act requires an assessment of adverse effects on the environment including impacts to shellfish beds, fishery areas, and wildlife prior to approval of discharges from dredge and fill activities.

Several provisions under the 1987 Amendments to the Clean Water Act require an assessment of environmental impacts. Under Section 304(a), EPA must develop methods, including biological monitoring and assessment methods, for establishing and measuring water quality criteria for toxic pollutants. The 1987 Amendments to the Act also establish, under Section 320(b), an estuary protection program that includes the development of a management conference to implement the program. The purpose of a management conference is to collect and assess data on toxics, nutrients, and natural resources within the estuarine zone to locate the causes of environmental problems.

1.4 Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)

The objective of the Federal Insecticide, Fungicide, and Rodenticide Act is to prevent "unreasonable adverse effects on the environment" from the use of pesticides. Although ecological assessments are not explicitly required, the components for protection of the environment are generally provided for through definitions provided in FIFRA. Specifically, the environment is defined under FIFRA to include "water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these." Unreasonable adverse effects on the environment are defined under FIFRA as any "unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits."

Section 3 of FIFRA establishes the procedures by which a pesticide is registered. Section 3(c) specifies that prior to approval of a registration, an assessment of the impacts of the use of a pesticide on the environment must be performed by the Administrator. Under Section 3(d), the potential for a pesticide to adversely effect the environment if improperly used is the primary factor the Administrator must consider when classifying pesticides for general or specific use. For pesticides not previously registered, the Administrator can issue an experimental use permit under Section 5 of FIFRA that would contain conditions for use. The Administrator may require, as a condition to the permit, studies to detect whether the pesticide under the permit may cause unreasonable adverse effects on the environment.

In addition to setting forth criteria for pesticide classification and use, FIFRA specifically calls for assessments of environmental effects of pesticide use. For example, Section 20(c) of FIFRA requires, as necessary, monitoring of air, soil, man, plants, and animals to assess incidental pesticide exposure.

Finally, Section 25 of FIFRA provides the Administrator with the authority to prescribe regulations to control the development and use of pesticides. These regulations must account for the differences in environmental risk and data for evaluating such risk between agricultural and nonagricultural pesticides.

1.5 Marine Protection, Research, and Sanctuaries Act (MPRSA)

Title I of the Marine Protection, Research, and Sanctuaries Act establishes a program to regulate the disposal of waste in the ocean in order to protect human health, welfare, and amenities, and the marine environment, ecological systems, and economic potentialities. Section 102 of MPRSA requires an assessment of the impacts of ocean dumping activities on the environment prior to issuance of a permit. According to Section 102(a), some of the factors that the Administrator must consider in issuing permits for disposal are the effects of the ocean dumping activity on fisheries resources, plankton, fish, shellfish, wildlife, shore lines and beaches; potential effects on marine ecosystems; and potential changes in marine ecosystem diversity, productivity, and stability. Under Section 102(c), the Administrator can designate recommended dumping sites or times in order to protect critical areas. This designation is to be based upon the same considerations required under Section 102(a), including in part the effects of the dumping on fisheries resources, plankton, fish, shellfish, etc.

Title II of the Act requires comprehensive research projects on the effects of ocean dumping on marine environments. Section 202(a)(2) calls for the assessment of scientific technologies to define and quantify the degradation of the marine environment, the assessment of the capacity of the marine environment to receive materials without degradation, and continuing monitoring programs to assess the health of the marine environment.

Title III establishes the National Marine Sanctuaries Program. According to Section 303(b), the criteria for determining whether an area will be designated as a sanctuary include the natural resources and ecological qualities of an area, such as biological productivity, maintenance of ecosystems structure, and maintenance of ecologically or commercially important or threatened species. The present and potential activities that may also affect the natural resources and ecological qualities of an area must also be considered.

1.6 Resource Conservation and Recovery Act (RCRA)

The objectives of RCRA are to promote the protection of human health and the environment and to conserve valuable material and energy sources. Although neither the Act nor its legislative history define protection of the environment, there are several provisions under RCRA that could necessitate an assessment of environmental impacts. Section 1008 requires EPA to develop guidelines that provide levels of performance of solid waste management practices that would provide for the protection of public health and the environment. Requirements to protect the environment are contained in various subsections of Section 3004, Standards Applicable to Owners and Operators of

Hazardous Waste Treatment, Storage, and Disposal Facilities. Specifically, determinations by EPA for the prohibition or regulation of various solid waste management practices and associated hazardous wastes must account for protection of the environment. For example, Section 3004(b) prohibits the use of underground mines for the storage or disposal of hazardous wastes unless EPA determines that such placement is protective of human health and the environment.

Under Subtitle H of RCRA, various studies are required to conduct research, demonstration, and training related to solid waste management practices in an effort to improve practices and reduce adverse environmental effects.

1.7 Safe Drinking Water Act (SDWA)

The purpose of the SDWA is to assure that all public drinking water systems provide safe, high quality water. Although the primary goal of the SDWA is protection of public health, one provision requires an environmental assessment. Section 1427 of the Act requires that EPA develop criteria for the identification of critical aquifer areas that should receive special protection. In developing the criteria for this identification, the environmental costs and benefits must be considered. The specific factors associated with the assessment of environmental costs and benefits are not provided for in the Act itself, nor are they discussed or interpreted in the legislative history of the Act.

1.8 Toxic Substances Control Act (TSCA)

The objective of TSCA is to protect human health and the environment through the regulation of the manufacture and use of chemical substances. The specific methods that are necessary to assure protection of the environment are not provided in the Act. Environmental assessments could be required based upon the definition of environment provided under the Act. The environment is defined in TSCA to include "water, air, and land and the interrelationship which exists among and between water, air, and land and all living things."

One of the primary means of protection established under TSCA is requiring test data under Sections 4 and 5. This test data must show that the manufacture, processing, distribution, use, and disposal of substances will not present any unreasonable risk of injury to health or the environment. Section 4 of TSCA requires the submission of test data for substances that have been included on the priority list, established pursuant to Section 4(e). Section 5 requires notification of the intent to manufacture or process any chemical substance. For the manufacture of a new chemical substance or new uses of an existing chemical substance, test data must be submitted along with the notification. Exemptions for notification to manufacture or process a chemical substance can be granted under Section 5(h) for test marketing purposes. However, this exemption can be granted only after it is demonstrated that the manufacture or use of the substance will not present any unreasonable risk of injury to health or the environment.

Section 6(e) of TSCA requires the establishment of regulations to specifically control the manufacture and use of polychlorinated biphenyls. Under Section 6(e), the Administrator is authorized to permit the manufacture, process, distribution, and use of polychlorinated biphenyls in a manner that is not totally enclosed only if it is shown that the practice will not pose an unreasonable risk of injury to health or the environment.

2.0 STATUTES AND DIRECTIVES ADMINISTERED BY OTHER FEDERAL AGENCIES

Table B-2 provides a summary of ecological assessment requirements of environmental legislation administered by Federal agencies other than EPA. A brief description of the ecological risk assessment requirements for each statute and directive is provided below.

2.1 Coastal Zone Management Act of 1972

The purpose of the Coastal Zone Management Act of 1972 is to encourage and assist States to develop and implement management programs to protect the land and water resources of the coastal zone, considering in part the ecological values of the coastal zone. Although ecological assessments are not specifically required under this Act, it may be appropriate for an assessment of ecological risks to be performed as part of a coastal management program established pursuant to the Act.

2.2 Endangered Species Act

The objective of the Endangered Species Act is to conserve the ecosystems upon which endangered or threatened species depend, and to conserve the species themselves. In determining whether or not a species is considered endangered or threatened, Section 4(a) requires that the present or potential destruction, modification, or curtailment of a species habitat or range, and other natural and manmade factors affecting the existence of the species, be assessed. Further, under Section 7, any Federal agencies that undertake activities that may jeopardize the continued existence of an endangered species must perform a biological assessment to identify the endangered species which is likely to be affected by the activity. The specific form of the biological assessment is not specified in the Act.

2.3 Executive Order 11988, Floodplain Management

Executive Order 11988 requires that agencies of the Federal government take actions to reduce the risk of flood loss; minimize the impacts of flood loss; minimize the impacts of floods on human safety, health, and welfare; and restore and preserve the natural and beneficial values served by floodplains. Although ecological assessments are not specifically required, any major Federal actions involving floodplains must be accompanied by an environmental impact statement as required under the National Environmental Policy Act (discussed further below).

2.4 Executive Order 11990, Protection of Wetlands

Executive Order 11990 requires that Federal agencies take actions to minimize the destruction, loss, or degradation of wetlands, and to preserve and enhance the natural and beneficial values of wetlands. According to Section 5(b), prior to any Federal activity involving wetlands, the appropriate Federal agency must consider the effect of the activity on the maintenance of the natural system, including productivity of existing flora and fauna, species and habitat diversity and stability, hydrologic utility, and fish, wildlife, timber, food, and fiber resources.

TABLE B-2

SUMMARY OF THE LEGAL MANDATE FOR ECOLOGICAL ASSESSMENT (OTHER FEDERAL AGENCIES)

Legislation	**Applicable Section(s)**	**Activities For Which Ecological Assessment Required/Recommended**	**Citation Summary**
Coastal Zone Management Act of 1972	303	Declaration of policy	Encourage and assist States to develop and implement management programs to achieve wise use of the land and water resources of the coastal zone, giving full consideration to ecological values, etc.
Endangered Species Act	4(a)	Determination whether any species is an endangered or threatened species	Factors to be considered include, in part; the present or threatened destruction, modification, or curtailment of its habitat or range, and other natural or manmade factors affecting its continued existence.
	7(c)	Federal activities that may jeopardize the continued existence of any endangered species.	If an endangered species may be present in an area of proposed Federal activity, then a biological assessment will be required to identify the endangered species which is likely to be affected.
E.O. 11988 Floodplain Management	1 2(a)	Federal activities involving floodplains including: 1) Acquiring, managing, and disposing of Federal lands and facilities; 2) Providing Federally undertaken, financed, or assisted construction and improvements; and 3) Conducting Federal activities and programs affecting land use, including but not limited to water and related land resources planning, regulating, and licensing activities.	Required to minimize the impacts to floodplains and to restore and preserve the natural and beneficial values served by floodplains. Major Federal actions involving floodplains must submit an environmental impact statement as required under NEPA.
E.O. 11990 Protection of Wetlands	1(a) 5(b)	Federal activities involving wetlands including: 1) Acquiring, managing, and disposing of Federal lands and facilities; 2) Providing Federally undertaken, financed, or assisted construction and improvements; and	Required to minimize the destruction, loss or degradation of wetlands. Prior to construction, required to consider in part the effect of the activity on the maintenance of natural systems, including conservation and long term productivity of existing flora and fauna, species and habitat diversity and stability, hydrologic utility, fish,

TABLE B-2 (Continued)

SUMMARY OF THE LEGAL MANDATE FOR ECOLOGICAL ASSESSMENT (OTHER FEDERAL AGENCIES)

Legislation	Applicable Section(s)	Activities For Which Ecological Assessment Required/Recommended	Citation Summary
E.O. 11990 Protection of Wetlands (continued)		3) Conducting Federal activities and programs affecting land use, including but not limited to water and related land resources planning, regulating, and licensing activities.	wildlife, timber, and food and fiber resources.
Fish and Wildlife Coordination Act	2	Projects involving impounding, diverting, or controlling waters	Must submit a report that describes the damage to wildlife attributable to the project and an estimation of the wildlife benefits or losses.
	5	Investigations to determine the effects of domestic sewage, mine, petroleum, industrial wastes, and other polluting substances on wildlife.	Fish and Wildlife Service and Bureau of Mines authorized to make such investigations and report to Congress. Investigations shall include in part the determination of standards of water quality for the maintenance of wildlife.
NEPA	102	Any planning or decision-making by Federal agencies which may have an impact on man's environment	Require integrated use of the natural and social sciences and environmental impact statements for every recommendation or report on proposals for legislation and other major Federal actions.
	204	Preparation of the annual Environmental Quality Report by the Council on Environmental Quality	Required to conduct investigations, studies, surveys, research, and analyses relating to ecological systems and environmental quality.
Wild and Scenic Rivers Act	1271	Declaration of Policy	Policy to preserve selected rivers in their free-flowing condition, to protect the water quality of such rivers, and to fulfill other vital national conservation purposes.

2.5 Fish and Wildlife Coordination Act

The objective of the Fish and Wildlife Coordination Act is to assist in developing and protecting all species of wildlife, wildlife resources, and wildlife habitat. Several sections under this Act appear to require an ecological assessment. Specifically, Section 2 of the Act requires a report, for projects involving impounding, diverting, or controlling waters, which describes the damage to wildlife attributable to the project and measures proposed for mitigating or compensating for these damages. In addition, the report has to include an estimation of the wildlife benefits or losses to be derived from any new project for the control or use of water. Under Section 5 of this Act, the Fish and Wildlife Service and the Bureau of Mines are authorized to perform investigations to determine the effects of pollutants on wildlife including the determination of standards of water quality for the maintenance of wildlife.

2.6 National Environmental Policy Act (NEPA)

The objective of NEPA is to preserve and enhance the environmental quality of the Nation. To ensure that the objective is achieved, all Federal agencies are required to submit a report, for proposed legislation or major Federal actions that could have a significant impact on the environment, that describes the environmental impact, any adverse environmental effects, etc. The Act does not specify the form of the analysis necessary, nor does it define environment. However, these studies usually include an analysis of the impact on soils, geology, hydrology, air quality, and wildlife. The Council on Environmental Quality, established under Title II, is also required to conduct investigations, studies, surveys, research, and analyses relating to ecological systems and environmental quality. The Council must present an Environmental Quality Report to Congress on an annual basis. This report sets forth the status of the environment, including the air, marine, estuarine, and fresh water environments, and forest, dryland and wetland environments.

2.7 Wild and Scenic Rivers Act

The goals of the Wild and Scenic Rivers Act are to preserve selected rivers in their free-flowing condition, to protect the water quality of such rivers, and to fulfill other vital National conservation purposes. The Act designates the initial components (i.e., rivers) of the National Wild and Scenic Rivers System, and prescribes methods and standards according to which additional components may be added. Although there is no specific requirement for an ecological assessment in conjunction with the methods and standards provided, the stated goals indicate that ecological impacts should be considered under this Act.

APPENDIX C

ECOLOGICAL ASSESSMENT METHOD SUMMARIES

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INTRODUCTION

In this appendix, we present a review of twenty ecological assessment methodologies that have been developed for use by one or more Federal or State agencies. This is not a comprehensive list of available ecological assessment methodologies. The methodologies included in our review are representative of those used for three general types of applications: setting environmental criteria, setting priorities, and risk characterization for purposes of risk management.

We describe how the methodologies characterize ecological targets, hazard, exposure, and risk. The reviews are organized by the legal mandates under which the methodologies were developed. Methods developed under CERCLA are presented first, followed by those developed under the Clean Air Act, Clean Water Act, FIFRA, RCRA and TSCA. Several other methodologies, not developed under any specific legal mandate, also are included in this review.

1.0 METHODS/ASSESSMENTS DEVELOPED UNDER CERCLA

1.1 CERCLA TYPE A DAMAGE ASSESSMENT FOR COASTAL AND MARINE ENVIRONMENTS (DOI 1987a)

1.1.1 Introduction

The Department of the Interior (DOI) has developed procedures for assessing damages to natural resources from a discharge of oil or a release of a hazardous substance compensable under either CERCLA or the Clean Water Act. Under CERCLA, states or the Federal government can assert claims for compensation for natural resource damage or injury following discharge of oil or hazardous substance release. The Natural Resource Damage Assessment Model for Coastal and Marine Environments (NRDAM/CME) was developed for damage assessment following a single, relatively small (type A) release in coastal and marine environments. The model is an interactive computer program that generates a measure of damages based on information regarding the nature, date, and location of a hazardous material release. Minimal field observations are required.

In the NRDAM/CME model, damages are defined as diminution in the use value of natural resources resulting from injuries caused by a discharge or release. Damages are equal to the difference in the *in situ* resource values pre- and post-incident.

As Figure C1-1 illustrates, the model comprises three major submodels and data bases. The physical fate and transport submodel simulates the spread of contaminants from a discharge source over time and space. The biological submodel estimates both direct and indirect effects on plants and animals. (Direct effects include contaminant-induced mortality; indirect effects include lost productivity in higher trophic levels as a consequence of mortality in lower trophic levels and reduced recruitment of larvae and juveniles.) The economic submodel estimates damages to commercial and recreational fisheries. Damages to public beaches, waterfowl, shorebirds, seabirds, and marine mammals are also estimated. Biotic effects such as reduced growth rates, lost reproductive potential, increased susceptibility to other biotic stresses (e.g. disease, parasitism), or competitive relationships between species are not addressed.

1.1.2 Description of Method

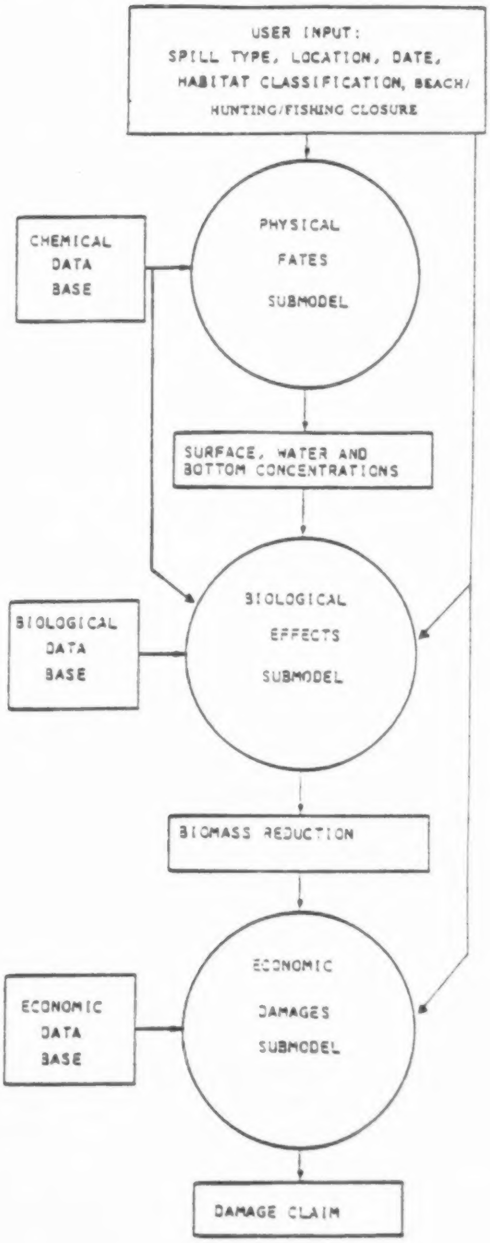
Receptor Characterization

Receptor characterization under the NRDAM/CME model is limited to coastal and marine environments. Within these environments, a variety of marine and coastal biomes are represented. Coastal waters are divided into ten regions

FIGURE C1-1

NRDAM/CME MODEL

(Source: DOI 1987a)


USER INPUT:
SPILL TYPE, LOCATION, DATE,
HABITAT CLASSIFICATION, BEACH/
HUNTING/FISHING CLOSURE
CHEMICAL DATA BASE
PHYSICAL FATES SUBMODEL
SURFACE, WATER AND BOTTOM CONCENTRATIONS
BIOLOGICAL DATA BASE
BIOLOGICAL EFFECTS SUBMODEL
BIOMASS REDUCTION
ECONOMIC DATA BASE
ECONOMIC DAMAGES SUBMODEL
DAMAGE CLAIM

or provinces which are further divided according to tidal position (i.e., intertidal/subtidal) and bottom type (e.g., rock, sand, coral). For each of the resulting 91 ecosystem types, there are four categories of data: (1) adult biomass by species; (2) larval numbers by species category, (3) mortality and growth parameters by species category; and (4) primary and secondary productivity values.

Biological receptors are divided into categories: six fish species groups, three invertebrate groups, three bird groups, and one mammal group. The fish groups include anadromous, planktivorous, piscivorous, demersal, and semi-demersal fish and top carnivores. Three life stages are considered for fish and invertebrates: egg/larval, juvenile, and adult. Shorebirds, seabirds, waterfowl, and fur seals are represented by two life stages (adults and young). Primary producers (e.g., phytoplankton, benthic micro- and macroalgae, and higher plants) and zooplankton are also considered. Seasonally dependent parameters considered in receptor characterization include temperature, adult and juvenile biomass by species group, abundance of birds and mammals (and their young), number of larvae, and primary productivity.

Hazard Assessment

The model includes toxicological data for 469 substances. Hazard assessments for fish, invertebrates, zooplankton, and phytoplankton are conducted using LC_{50} and EC_{50} data. A hazard value for each species group is derived by dividing the acute toxicity value by a safety factor of 100 to estimate a no-effect level. This approach assumes that the same dose-response relationship holds for all hazardous substances. Hazard values were derived in this manner for five organism groups: (1) adult and juvenile fish, (2) adult and juvenile benthic invertebrates, (3) larvae of fish and benthic invertebrates, (4) zooplankton, and (5) phytoplankton and other primary producers. For fish and invertebrates, the acute LC_{50} values in the data base were standardized to 25 degrees Centigrade and 96 hours of exposure. Sources of uncertainty surrounding the hazard values are not addressed.

This hazard assessment methodology includes consideration of the effects of temperature and duration of exposure (if less than 4 days) on the population response to a particular toxicant concentration For exposures lasting more than 4 days, the 4-day LC_{50} is used.

Toxicant-induced effects on primary productivity also are considered in the hazard assessment. Decreases in primary productivity are estimated from EC_{50} data using a log-normal toxicity model. Decreases in productivity are assumed to be independent of exposure duration.

Potential hazards to other organisms are based on more limited data. Birds and fur seals are assumed to be affected only by those substances that form surface slicks (petroleum products in most cases). Based on available data, it is assumed that a fixed proportion of birds and seals that are oiled (according to the exposure submodel) will die (38% and 63%, respectively).

The uncertainty around these estimates, either as representative means or environmentally dependent variables, is not addressed.

Exposure Assessment

The physical fates submodel estimates the distribution of a contaminant on the sea surface, in the water column (partitioned as upper and lower), and in the sediments. The user must enter specific information concerning the spill (e.g., type and amount of substance spilled, regional province, and bottom type). The chemical data base of 469 compounds contains empirical or estimated values for parameters used in the fate and transport model (e.g., solubility, degradation rate in water and sediments, and viscosity).

The model is designed to simulate the fate of pure hazardous substances, crude oils, and petroleum products. Crude oil and petroleum products are represented by four components: (1) low molecular weight aromatics (50/50 mixture of benzene and toluene); (2) medium molecular weight aromatics (100-160 g/mole); (3) an insoluble but volatile portion; and (4) a residual fraction which is neither soluble nor volatile.

The time course of events is modeled using incremental time steps scaled with respect to the size of the spill. Spatial variation is similarly modeled with a variable-sized horizontal grid. The space in which the toxicant concentration is estimated to be greater than the toxicity threshold is divided into ten spatial volumes horizontally in each of three layers (upper water column, and lower water column, if appropriate; and sediments).

The concentration estimation methods consider several processes affecting contaminant movement within and between compartments. Contaminants on the ocean surface spread under the influence of wind, currents, temperature, viscosity, evaporation, thickness of surface slick, and dissolution into the water column. Contaminants within the water column are transported horizontally by current movement and dispersion. Contaminants with a specific gravity greater than seawater are modeled by a convective descent algorithm. Contaminants that reach the seafloor enter the sediments via bioturbation (e.g., bottom fish foraging). The particulate and interstitial concentrations of the contaminant are modeled separately. Dissolution of contaminants from the sediment into the water column is modeled. Degradation is modeled in both the water column and sediments. For substances spilled in the intertidal area, the model calculates the area impacted and a removal constant which accounts for dissolution, evaporation, and degradation. All processes are deterministic except for vertical dispersion which is simulated as a random walk. Other sources of uncertainty are not developed or propagated.

Risk Characterization

The biological effects submodel of the NRDAM/CME model combines the quantitative exposure assessment model results with the biological data base and indicates the numbers and biomass of organisms affected. The submodel estimates both short- and long-term losses to each of the biota (receptor) groups. Short-term losses include mortality that is a direct result of exposure to toxicant concentrations above threshold. Long-term losses include lost recruitment of larvae and juveniles into the breeding populations as well as reduction in productivity at higher trophic levels as a result of lost primary and secondary production. Other, more complicated biotic relationships, such as competitive release and density-dependent predator-prey population effects, are not included in this model because of the lack of a strong empirical and theoretical framework for such analyses.

Single contaminants or petroleum products that are compartmentalized into four subgroups can be modeled. Exposure pathways include the water surface, water column, and sediments but not the transfer of toxicants up the food chain. The environmental injury submodel is sufficiently simple to be generally applicable across coastal and marine environments. It is sufficiently complex to incorporate several levels of effects.

Short-term losses are calculated in the acute toxicity submodel. This model estimates the fraction of each population (organism class) exposed to a given concentration that die based on the appropriate LC_{50} value, temperature, and duration of exposure (if less than 4 days). The biomass of each category of organism is obtained from the biological data base. As time progresses, more organisms are exposed to the expanding contaminant plume. In addition, fish are assumed to swim into and out of the plume, thus exposing even more individuals. Behavioral avoidance of the contaminant plumes is not considered.

Long-term losses depend upon (1) lost primary and secondary production and (2) lost recruitment of larvae and juveniles. Reduced primary production is estimated for phytoplankton and macroalgae, when appropriate, using EC_{50} information. The reduction is passed on to two classes of secondary production: zooplankton and benthic invertebrates. Direct losses of secondary producers from toxic effects are also calculated, and the larger of the two types of losses (indirect through reduced primary production and direct mortality) is used. This assumes that the growth of zooplankton will either be food-limited or toxicant-limited, but not both.

Lost primary and secondary productivity is translated into lost yield for each animal species category via reduced food supply using a simple food web model which is illustrated in Figure C1-2. The model is based on simplifying assumptions which are applicable to all environments.[1]

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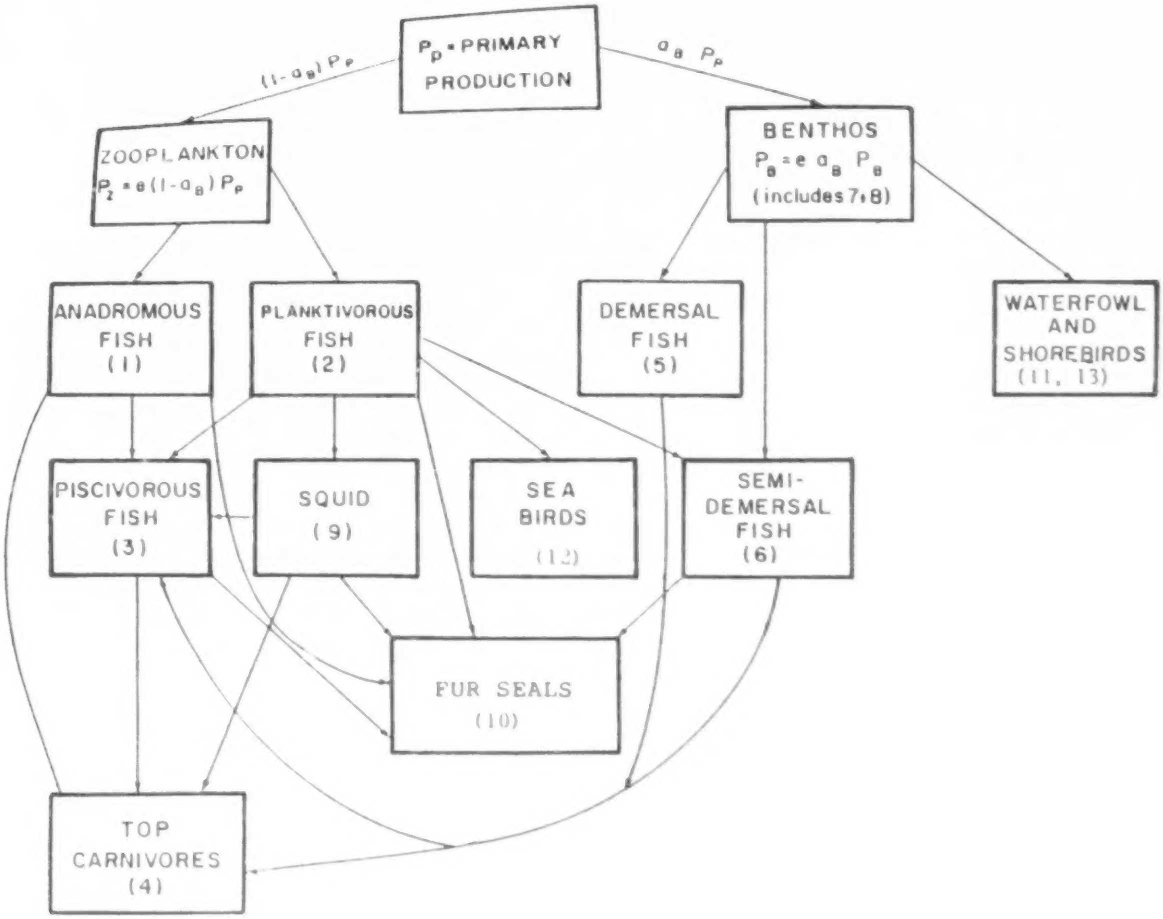
[1] Food chain efficiencies are assumed to be 20 percent. The food web model assumes that the share of each prey item that a predator consumes is proportional to its biomass relative to all other predators of that prey. Larvae of fish and benthic invertebrates are assumed to feed entirely on zooplankton and to be food-limited.

FIGURE C1-2

FOOD WEB MODEL FOR CERCLA TYPE A ASSESSMENTS
(Source: DOI 1987a)


(1-a_B) P_P
P_P = PRIMARY PRODUCTION
a_B P_P
ZOOPLANKTON
P_Z = e(1-a_B) P_P
BENTHOS
P_B = e a_B P_B
(includes 7+8)
ANADROMOUS FISH (1)
PLANKTIVOROUS FISH (2)
DEMERSAL FISH (5)
WATERFOWL AND SHOREBIRDS (11, 13)
PISCIVOROUS FISH (3)
SQUID (9)
SEA BIRDS (12)
SEMI-DEMERSAL FISH (6)
FUR SEALS (10)
TOP CARNIVORES (4)

Productivity and rates of transfer of energy from lower to upper trophic levels are province-specific and vary by estuarine or marine environment, by bottom type, and by season.

Reduction of larval populations, either directly or indirectly, is translated into long-term catch losses using a fisheries model. Density-dependent population dynamics are not incorporated. Other adverse effects modeled include loss of waterfowl for hunting, losses of birds for recreational purposes (i.e., bird watching), lost fur seal production, and closed beaches.

Once measures of specific categories of injury have been estimated, the economic damages submodel places a dollar value on each type of loss. Damages to lower trophic biota, for which use or market values do not exist, are translated through the food web into reductions in species of monetary value. Region-specific valuations of commercial fish species are included. The lost in situ value of each biological compartment is calculated separately for each year.

Although sections of the model might be amenable to field validation, it is unlikely that the effort involved would be appropriate. A more cost-effective approach would be through verification of the algorithms and sensitivity analyses. The sensitivity analyses presented by the authors illustrated the following. Economic damages increased linearly with the amount of contaminant spilled. Damages from the same size spill depended upon season and province, with winter Arctic coastal spills three orders of magnitude less costly than spring spills in the California estuarine environment. In addition, the economic damages varied dramatically with the physical/chemical properties of the substance spilled.

1.1.3 Operational Resource Requirements

The NRDAM/CME model can be run on a personal computer, and can be obtained on a series of four diskettes along with the documentation from NTIS. These diskettes include all associated data bases for the ecological regions and environments and complete data bases for 469 chemical compounds. With a minimum of information concerning an actual spill, the model is very easy to run. The high cost and effort required to develop a model of this type has already been invested. It is not known if the NRDAM/CME model will be updated in future years. The computer time required to analyze a single spill depends in large part on the size of the spill and can range from 10 minutes for small spills (e.g., < 10 metric tons) to over an hour for large spills (e.g., > 500 metric tons).

1.1.4 Summary

The NRDAM/CME modeling approach is based entirely on acute toxicity data for five general classes of organisms for each compound in the chemical data base. From these data and a simple food-web model, population effects for several categories of animals and plants are determined. When the empirical data indicate that an effect is highly variable in the real world, a "best" case estimate rather than a worst case estimate is selected as the input value. All output parameters are also represented by single values. No attempt is made to incorporate the uncertainty in either value measurements or in the real world. Considering the sizable data bases and the number of estimations, extrapolations, and assumptions, providing an analytic characterization of uncertainty from all sources would be difficult.

The NRDAM/CME methodology is a relatively sophisticated approach to ecological damage assessments for coastal and marine natural resources. In the context of providing a framework for Type A damage assessments for CERCLA, the final endpoints of concern are translated into economic losses. Nonetheless, a wide diversity of endpoints are considered, analyzed, and presented along with the final monetary evaluations.

1.2 TYPE B NATURAL RESOURCE DAMAGE ASSESSMENT (DOI 1987b)

1.2.1 Introduction

The Department of the Interior (DOI) has developed procedures for measuring damages to natural resources resulting from a discharge of oil or a release of a hazardous substance compensable under either CERCLA or the Clean Water Act. The Type B damage assessment procedure is intended to provide guidance for conducting site-specific assessments based on data collected in the field. The procedure is different from the other assessment methodologies included in our review because it focuses on field measurements of impacts that have already occurred, rather than the probability that impacts will occur. Therefore, hazard and exposure assessments, typical components of ecological risk assessments, are not conducted, nor is there a risk model/method to combine hazard and exposure information. Nevertheless, the damage assessment procedures provide some conceptual approaches that may be potentially applicable to ecological risk assessment.

Type B natural resource damage assessments involve three major steps: establishing that an injury has occurred and that the injury resulted from a discharge or release; quantifying the effects of the discharge or release; and determining the damage. Injury is defined as a measurable adverse change in the chemical or physical quality or viability of a natural resource. Damage is defined as the amount of money sought by the Federal or state agency acting as trustee for the natural resource to compensate for the loss. Natural resources include surface water, ground water, geological resources (soil, rocks, and minerals) and biological resources. Injury is defined uniquely for each natural resource and is documented following collection of field or laboratory data and statistical analysis.

1.2.2 Description of Method

Receptor Characterization

Potential receptors include representative components of the entire biosphere; both the biotic (aquatic and terrestrial) and abiotic components (air, land, water) of ecosystems are considered. Assessments of biological injury are conducted at the population level.

Hazard Assessment

As discussed previously, the damage assessment does not have a "true" hazard assessment procedure. However, the definition of injury for each natural resource may be useful in characterizing hazard assessment endpoints for ecological risk assessments.

Injury to surface water and ground water occurs when the water concentrations of substances are in excess of Federal or State drinking water standards or water quality criteria, or are sufficiently elevated to cause damage to other natural resources. Also, an injury has occurred if the substance's concentration in bed, bank, or shoreline sediments is sufficient to cause the sediment to exhibit characteristics of hazardous waste (as defined under RCRA).

Injury to air occurs if the concentrations of emissions are in excess of standards for hazardous air pollutants established by Federal or State regulations or if the concentrations are sufficient to cause injury to other natural resources.

Injury to geologic resources occurs if the concentration of a substance in the geologic resource is sufficient to cause damage to other natural resources or is sufficient for the materials in the geologic resource to exhibit the characteristics of hazardous wastes (as defined under RCRA). Also an injury has occurred if the concentration of a substance is sufficient to alter soil pH, salinity, or water-holding capacity beyond prescribed levels, to impede soil microbial respiration and soil carbon mineralization, or to cause a toxic response in plant or soil invertebrates.

A biological resource is injured if it or its offspring have undergone at least one of the following changes in viability: death, disease, behavioral abnormalities, cancer, genetic mutations, physiological malfunctions, or physical deformations.

The method for determining injury is limited by the capability of the method to demonstrate a measurable biological response. According to the criteria established by DOI, only certain procedures within the six injury categories are sufficient to demonstrate an injury to a biological resource. These are discussed briefly below by injury type. In all cases, measured responses in injured populations must be statistically different from control populations.

Death. Death can be measured in both fish and wildlife. Three acceptable measures of death in fish are fish kills, in situ bioassays using cultured or indigenous fish, and laboratory tests of acute or subchronic toxicity. The only acceptable approach to document oil or hazardous substance related death in wildlife is a brain cholinesterase inhibition of at least 50% in field populations compared with control populations. Lesser inhibition, but in excess of 20%, can be considered contributory to death provided that such inhibition is statistically separable from controls.

Disease. Acceptable approaches for documenting disease injury in fish are limited to fin erosion and lesions on fish tissue. Acceptable approaches for documenting disease in wildlife populations are not available.

Behavioral abnormalities. Procedures adequate to document behavioral changes in fish are limited to laboratory studies of behavioral avoidance in species representative of site conditions and observations of clinical behavioral signs of toxicity. For wildlife, injury has occurred if there is a statistically significant increase in observations of clinical behavioral abnormalities in field populations versus controls, or if two or more specimens display behavioral abnormalities while none do in the control populations.

Cancer. Statistically significant increases of liver or skin neoplasia are sufficient to document cancer injury in fish. Injury determination in fish can be documented via field sampling of natural populations or bioassays using water from the potentially affected area and standard laboratory assay species. No acceptable procedures have been identified to document cancer injury in wildlife populations.

Physiological malfunctions. Altered physiologic parameters accepted as adequate documentation of physiologic malfunctions are reduced reproduction in fish; and egg shell thinning, reduced reproduction, reduction in brain ChE, and decreased delta amino levulinic acid dehydratase (delta ALAD) in birds and mammals.

Physical deformations. Injury from physical deformations can be documented in wildlife if there is an increased incidence of external malformations, skeletal malformations, internal whole organ and soft tissue malformations, or histopathological effects between suspect polluted locations and control areas. No such measures were identified as adequate for documenting physical deformation injury in fish.

Exposure Assessment

An exposure assessment is not included in the damage assessment. Although the regulations stipulate that exposure pathways must be delineated, specific procedures to document a pathway are not provided.

Risk Characterization

This method does not include a risk model/method. However, procedures to quantify damages by establishing a dollar value for the injury have been outlined. Quantification of injury to biological resources can be based on changes in populations (often quantified by numerical counts of injured individuals) or on changes in ecosystems or habitats. The Fish and Wildlife Service has proposed the use of habitat evaluation procedures (HEP) to quantify changes in fish and wildlife habitats. HEP is an accounting procedure for tracking an integrated measure of habitat quality and surface area of habitat. The integrated measure is called a Habitat Unit (HU). The number of HUs is defined as the product of the Habitat Suitability Index (HSI) and the area of available habitat. HSIs and HUs are calculated for certain "evaluation species". The procedure can be used to quantify reductions in habitat quality between a polluted area and a control area.

1.2.3 Operational Resource Requirements

The damage assessment procedure is a relatively labor- and cost-intensive approach because field sampling and/or laboratory testing and economic analyses are required. Theoretically, selected aspects of this approach could be modified and applied to ecological risk assessments. However, the operational resource requirements of a modified approach cannot be evaluated at this time.

1.2.4 Summary

The DOI Type B damage assessment regulations provide procedures for injury determination. These procedures, however, are not ecological risk assessment procedures, and are therefore limited in their applicability for risk assessment. However, compilation of data from Type B damage assessments could provide valuable case-study data for risk assessment. In addition, the method does offer some unique approaches to define ecological injury. For example, under these procedures receptors include both biotic and abiotic ecosystem components. Many ecological risk assessment methodologies consider only how changes in the abiotic component can impact the biotic components of the ecosystem. The approach offered by DOI is unique in that abiotic ecosystem components are recognized as important resources irrespective of the associated biotic components.

The DOI damage assessment approach also considers the interactions between the abiotic and biotic components. Consideration of interactions between system components can loosely be considered an ecosystem approach. Although other approaches do consider ecosystem effects, implementation of the approach is not common.

2.0 METHODS/ASSESSMENTS DEVELOPED UNDER THE CLEAN AIR ACT

2.1 REVIEW OF THE NATIONAL AMBIENT AIR QUALITY STANDARDS FOR OZONE: STAFF PAPER (EPA/OAR 1986)

2.1.1 Introduction

The Office of Air Quality Planning and Standards (OAQPS) reviewed the secondary National Ambient Air Quality Standard (NAAQS) for ozone in their staff paper dated March 1986. The secondary standard is intended to be protective of both symptomatic health effects in humans and human welfare, including impacts on vegetation and natural ecosystems. Of particular concern are the adverse effects of ozone on plants. OAQPS identified short-term and long-term ambient ozone concentrations associated with low-effect levels for plants, and then evaluated whether certain criteria (e.g., the primary NAAQS for human health effects) would adequately protect agricultural plants and forests.

The approach used by OAQPS was not developed as a generic risk assessment methodology. We discuss it here because it is an example of the use of ecological risk assessment, and can in fact be used for other chemicals.

2.1.2 Description of Method

Receptor Characterization

The assessment focused on terrestrial plants, particularly crops and forest species, although aquatic systems were discussed briefly. Although OAQPS summarized the effects of ozone at the individual, population, and community levels, the exposure and risk assessments emphasized effects occurring at the population level.

Hazard Assessment

In the hazard assessment, concentrations of ozone that are toxic to plants were identified. Both qualitative and quantitative assessments were conducted. The qualitative assessment included descriptions of toxic endpoints and toxic concentrations at the ecosystem level (e.g., effects on aquatic systems bordering damaged forests), as well as at the population and individual levels (e.g., decreased photosynthesis). Response modifying factors such as water stress, nutrient deficiency, and pest and disease interactions also were discussed.

In the quantitative assessment, the hazard evaluation was limited to population-level effects on agricultural crops because of data limitations. Hazard was expressed in terms of air concentrations associated with phytotoxic responses. Hazard was evaluated for two concentration averaging periods: (1) a short-term peak expressed as a number of occurrences above a given level (multiple exceedances) and (2) a long-term average (expressed over a growing season of three months). For the short term assessment, a peak criterion of 0.08 ppm was selected because concentrations of this level or higher are definitely injurious to sensitive plant species when they are exposed for even short periods of time, usually less than one hour (Garner 1988). White pine has been used as an indicator species, injury being determined by visible foliar damage and growth measured by tree ring number and width. The long-term average criterion was derived primarily from yield-reduction experiments on crops. The protectiveness of the long-term standard to forest species was addressed qualitatively. Damage as used in the assessment is a chronic endpoint because it occurs over a lifetime (3-month growing season for crops, or tens of years for trees).

In the long-term hazard assessment, a 10% reduction in yield was used as the effect level of concern. The 10% level was chosen because it can be detected with some degree of confidence and is generally considered a significant effect. Long-term ozone concentrations associated with a 10% reduction in yield (0.04 to 0.05 ppm ozone) were determined from dose-response curves developed from experiments conducted as part of the National Crop Loss Assessment Network (NCLAN). This range of concentrations was then compared with data from greenhouse and controlled environment studies and with ambient air-exposure studies using crop species. The final range of concentrations associated with a 10% reduction in yield (0.04 to 0.06 ppm ozone) was presented as a 7-hour 3-month average. The 7-hour component of this average was chosen because it may correspond to the period of greatest plant sensitivity to ozone (0900-1600 hr). The three-month component might not be applicable to deciduous forests, and is not applicable to coniferous forests. Moreover, repeated short-term, high-level concentrations can be more injurious than continuous low-level ozone concentrations that represent the same "average" concentration (Garner 1988).

Exposure Assessment

Data from EPA's SAROAD (Storage and Retrieval of Aerometric Data) data base system were used to summarize current ozone concentrations in the United States and to predict future concentrations. Current concentrations of ozone were compared to the peak concentration of 0.08 ppm proposed in the hazard assessment as a short-term criterion based on phytotoxicity. Data gathered from 1982 to 1984 indicated that average hourly ozone concentrations in agricultural areas exceeded 0.08 ppm on the average 119 times each year. In remote areas, average hourly ozone concentrations exceeded 0.08 ppm on average 37 times each year. A series of longer-term averages were also presented.

The SAROAD ozone concentration data were also used to predict ozone concentrations that would result if the human-health-based peak criterion of 0.12 ppm were attained. Assuming peak ozone concentrations of 0.12 ppm, the percentage of days with hourly maxima exceeding 0.08 ppm were calculated, and the 7-hour, 3-month average concentration was estimated on the basis of significant (but weak) correlations between the second-highest daily maximum concentration, long-term concentrations and short-term peaks. Assuming a second-highest daily maximum of 0.12 ppm (corresponding to the human health criteria), there is a 10% chance that 32% or more of the days in a 3-month growing seasons will exceed a 7-hour, 3-month average of 0.08 ppm. A 7-hour, 3-month average concentration of 0.052 ppm was predicted with an upper bound (90%) estimate of 0.063 ppm.

Risk Characterization

Risk to terrestrial plants was evaluated qualitatively and focused on the risk associated with the human health-based peak criterion of 0.12 ppm. Both the daylight-hours seasonal mean and 90th percentile concentrations calculated based on attainment of the 0.12 ppm peak level were compared with the range of concentrations associated with effects. The degree of short-term risk to terrestrial plants was addressed by evaluating the percentage of days expected to exceed 0.08 ppm if the 0.12 ppm criterion were attained. Finally, the large uncertainty in the correlation between short-term and long-term ozone concentrations (coefficients of determination ranged from 0.3 to 0.4) was used to support the proposal of a long-term ozone standard in addition to the short-term standard.

The assessment has been partially calibrated since the hazard assessment was based in part on effects using ambient ozone levels and on field studies. Quantitative validation could be conducted using charcoal filtered ambient air studies.

2.1.3 Operational Resource Requirements

Data on the toxic effects of ozone were available for many major crop species and a few natural communities. The experimentation required to develop exposure-response curves for plant species was extensive and expensive, as was the data collection done to develop the statistics on ambient ozone concentrations. Therefore, application of this type of approach for ecological assessments of other chemicals is likely to be costly and labor intensive. Once these data have been developed, however, the cost and level of effort needed to estimate risk is low, and the assessment is straightforward.

2.1.4 Summary

The use of an extensive monitoring effort and exposure-response characterization is a powerful and useful combination. Limitations of this approach include the extrapolation from controlled experiments to plants growing in the field, and the emphasis on yield reduction as the toxic endpoint of concern. Strengths of this procedure are that it uses exposure-response modeling and considers temporal characteristics of the receptor. Also, community and ecosystem level effects as well as response modifying factors were qualitatively assessed.

2.2 AN ASSESSMENT OF THE RISK OF STRATOSPHERIC MODIFICATION (EPA/OAR 1987)

2.2.1 Introduction

The purpose of this probabilistic risk assessment was to aid the EPA Administrator in determining the need for additional controls on the releases of substances that may affect the stratosphere. The report assessed the likelihood that:

(1) different human activities would result in climate modification or in an alteration of the stratosphere's ability to filter ultraviolet radiation, and

(2) changes in ultraviolet radiation (UV-B) or climate due to modifications in column ozone or stratospheric water vapor would have detrimental effects on public health or welfare.

This review addresses only the ecological components of the overall assessment. Two physical effects of stratospheric modification were included in the ecological assessment: increased UV-B, and climate change/sea level rise. The general approach for assessing ecological risks from the two physical effects was similar. A deterministic model was used to estimate emissions and ozone depletion. Additional models were used to estimate the increase in UV-B and temperature attributable to the emissions. Exposure-response data or qualitative information was then used to estimate ecological effects. A generalized flow diagram is shown in Figure C2-1.

2.2.2 Description of Method

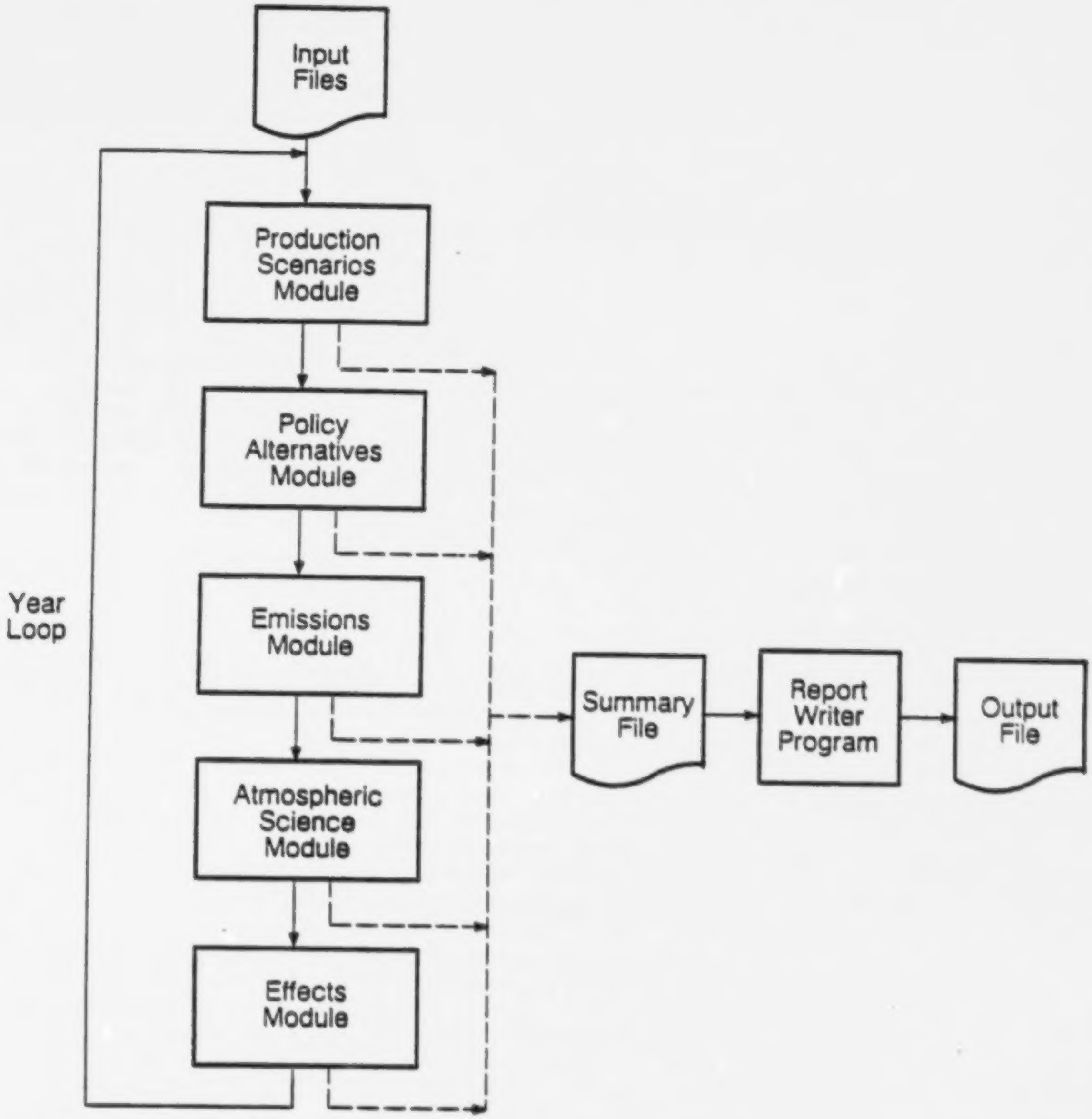
Receptor Characterization

Increased UV-B. Both aquatic and terrestrial receptors were considered under this approach. Although community-level endpoints were considered qualitatively, quantitative assessments were limited to the population level, primarily because of the paucity of exposure-response data for higher level effects. Single species were chosen as receptors for the quantitative assessments: soybeans in terrestrial systems and anchovies in aquatic systems. No attempt was made to generalize from these species to other species or levels of organization. Temporal characteristics of northern anchovies were discussed and incorporated into estimates of risk.

Climate Change/Sea Level Rise. The climate change assessment primarily addressed natural plant communities. Coastal wetlands, particularly those in Louisiana, Florida, Delaware, New Jersey, and Maryland, were identified as "receptors" of concern for potential effects of sea level rise.

FIGURE C2-1

GENERALIZED FLOW DIAGRAM FOR ASSESSMENT OF STRATOSPHERIC MODIFICATION
(Source: EPA/OAR 1987)


Input Files
Production Scenarios Module
Policy Alternatives Module
Emissions Module
Atmospheric Science Module
Effects Module
Year Loop
Summary File
Report Writer Program
Output File

Hazard Assessment

Increased UV-B. For the qualitative assessment of hazard to aquatic organisms, effects to a wide variety of species, including fish larvae and juveniles, shrimp larvae, crab larvae, copepods, and aquatic plants, were discussed; however, effects on planktonic organisms were emphasized. Most of the quantitative data available addressed anchovy mortality, but sublethal effects such as reduction in fecundity were also discussed. Temporal attributes of the organisms, particularly diel vertical movement of zoo- and icthyoplankton, were recognized as important uncertainties. Tolerance and avoidance mechanisms were also discussed. The most complete exposure-response data were available from laboratory tank experiments with anchovy larvae. These data were reinterpreted to include scenarios for vertical movement during the day by the larvae.

The assessment of effects on terrestrial organisms was limited to effects on plants. Little information was available for natural vegetation. Toxicity modifying factors such as mineral deficiency and water stress were discussed. Although effects on yield were emphasized, effects on yield quality and community-level effects, such as changes in plant competition and increases in disease and pests, were also discussed. The most complete exposure-response data were available for soybeans. The extrapolation from controlled experiments to effects in the field was recognized as a particularly significant source of uncertainty, but was not factored into the exposure-response quantification.

Climate Change/Sea Level Rise. The effects of climate change on plants were addressed using several methods. Paleovegetational records were analyzed to identify a possible historical analog to potential climate change, and present-day, vegetation-climate classifications of plant communities were discussed. In another approach, pollen abundances were correlated through regression techniques to climatic variables, such as temperature and rainfall. Response surfaces were then constructed. Such empirical response surfaces are available for many North American species. In general, the rate of climate change was identified as an uncertainty that has not yet been adequately addressed.

Another approach, still in the early stages of development, was the use of vegetation models that represent forest dynamics by a series of stochastic and deterministic equations. Exposure-response relationships based on empirical data or process-oriented theory were used to model the response of individual plant taxa. Currently these models are limited because the rate of climate change has not yet been considered, and because only North American communities have been modeled.

The discussion of effects of sea-level rise on wetlands emphasized effects on coastal wetlands, including inundation, salt-water intrusion, decline in peat formation, and shoreline erosion. Modifying factors, such as the degree of protection of shore-front property were also discussed.

Exposure Assessment

The exposure assessment component of the model is shown in the first four modules of Figure C2-1 and, for the purposes of this summary, also in part of the fifth module. Based on assumptions regarding production scenarios and policy alternatives, the emissions of stratospheric modifying gases were predicted. The atmospheric module then estimated the amount of ozone depletion associated with the emissions. The effects module estimated lateral ozone depletion from the one-dimensional model and estimated the amount of UV-B increase associated with the predicted depletion. The National Academy of Science mid-range estimate of climate sensitivity to a doubling of CO_2 was used to predict temperature change. Broad changes in sea level rise by the year 2100 were estimated for a range of warming scenarios.

Uncertainty in the exposure assessment was quantified in several ways in the different modules. Uncertainty in estimates of the production of stratospheric ozone-depleting gases was addressed by the use of five different sensitivity cases, using varying assumptions regarding future populations and economic growth. Different policy alternatives for controls on future use were specified. The output of the atmospheric module was presented as a range based on a given range of uncertainty for estimates of future population and economic growth.

Other uncertainties could not be quantitatively incorporated into the modules. For example, possible changes in technology were not included in the emissions module. The atmospheric module does not have the resolution to predict regional effects. Finally, factors that are as yet undefined or poorly understood, such as biogeochemical cycles, could not be incorporated.

Risk Characterization

The model is deterministic in that a unique output or result is produced by a specified input; there are no stochastic elements within the model. The exposure assessment component of the model estimated future emissions of stratospheric modifying chemicals. The resulting depletion of ozone, increase in UV-B, rise in equilibrium temperature, and rise in sea level were quantitatively modeled. The effects of increased UV-B on soybean yield and northern anchovy mortality rate were presented as ranges derived from case studies and on-going research. Changes in forest community structure were assessed qualitatively based on a doubled CO_2 scenario, but the rate of change was not considered. A range of percent coastal wetland loss in U.S. was estimated based on an analysis of topographic maps and wetlands inventories, and on a consideration of possible protection of shorefront property.

The model has been partially validated; current measurements of ozone were compared with model predictions. Because of the global nature of the problem, it will be very difficult to validate the predicted effects. However, the changes in plant communities predicted to occur with climate change could be validated/calibrated using historical (paleobotanical) data.

2.2.3 Operational Resource Requirements

The level of effort and expertise needed to develop the model was very high. As it exists now, a moderate level of effort, expertise, and a computer would be needed to use the model to adequately address different regulatory and gas production scenarios.

2.2.4 Summary

There are many limitations and uncertainties in the models, exposure-response curves, and effects data used to predict the effects of stratospheric modification. Nevertheless, the model provides a consistent framework by which different future scenarios and policy options can be evaluated. In addition, the approach is flexible enough so that changes or additional modules can be incorporated as the state of knowledge improves.

3.0 METHODS/ASSESSMENTS DEVELOPED UNDER THE CLEAN WATER ACT

3.1 GUIDELINES FOR DERIVING NUMERICAL NATIONAL WATER QUALITY CRITERIA FOR THE PROTECTION OF AQUATIC ORGANISMS AND THEIR USES (EPA/OWRS 1986)

3.1.1 Introduction

The Environmental Research Laboratories at Narragansett, Duluth, and Corvallis developed guidelines for the Office of Water Regulations and Standards (OWRS) for establishing limits to chemical concentrations in surface water that are protective of aquatic organisms, human health, and some recreational activities. The guidelines address the development of ambient water quality criteria (AWQC) for two measurement averaging periods: 1 hour and 4 days. These two criteria are known as the acute and chronic criteria, respectively.

3.1.2 Description of Method

Receptor Characterization

Aquatic organisms are the primary focus of this method. The methodology is designed to establish chemical concentration levels which, if not exceeded, should be protective of 95% of the species in the aquatic community. The method is designed for generic receptors, but can be modified to cover site-specific or locally-important species (e.g., commercially important species). Toxicity data from tests on the most sensitive life stage are recommended, but are not essential. Niche characteristics are not directly considered in the method unless field data for bioaccumulation of the chemical are available. The method is more fully developed for animals than for plants primarily because the test methodology is more refined for animal species.

Hazard Assessment

The methodology is designed to establish chemical concentrations which, if not exceeded more than once in three years, will be protective of 95% of aquatic species. The necessary data include acute and chronic toxicity data for animals and plants (including algae), bioconcentration or bioaccumulation factors, and either FDA tissue action levels or chronic wildlife feeding/field study results. The most rigorously defined criterion is the 1-hr maximum concentration. Data requirements for calculation of this criterion include toxicity data for animal species from a specified taxonomic range of orders and families. The maximum continuous concentration (4-day) value is taken as the lowest of either an animal chronic value, a plant toxicity value, or a tissue residue value.

The chronic toxicity value for aquatic animals can be calculated from chronic bioassay results in the same manner as the 1-hour maximum concentration, that is, by using toxicity data for animal species from a specified taxonomic range of orders and families. An alternative method is to use a chemical-specific acute:chronic toxicity ratio applied to the acute value derived above. The ratio method requires considerably fewer data than the chronic bioassay data set requirements. A toxicity value for plants is simply taken as the lowest reported toxic concentration for a plant or algal species. A specific plant toxicity endpoint is not specified. A tissue residue value is calculated from data on either FDA action levels or chronic wildlife feeding or field studies and bioconcentration or bioaccumulation factors.

Guidance is provided on appropriate test methods, test species, and life stages to be included in the data sets. Also, a regression method is included for calculation of acute and chronic toxicity levels when the toxicity of the chemical is affected by background water quality (e.g., water hardness). Salt and fresh water criteria are calculated separately. If a criterion is above a documented toxic threshold for a commercially or recreationally important species, the criterion can be replaced with the lower toxic level. The method is designed to calculate a criterion that corresponds to a value for a species representative of the lowest fifth percentile of species ranked according to sensitivity, and so is designed to be protective of 95% of the tested species. Guidelines are set for the development of single chemical criteria only; mixtures are not addressed.

Exposure Assessment

Exposure to aquatic organisms is assumed to occur only through water, although exposure to predators through the food chain is assessed by the residue value. The estimation or measurement of exposure in the environment is not a component of criteria development.

Risk Characterization

An assessment of the potential for adverse ecological effects can be conducted by comparing the criteria generated by the above method to concentrations of chemicals measured or estimated in the environment, as described in Sections 5.2 and 7.1.1. Criteria are not calculated for chemicals with insufficient taxonomic breadth in the available data. That the method is protective of 95 percent of aquatic species and that this level of protection prevents adverse ecosystem-level effects could be validated, but only by extensive field monitoring projects.

3.1.3 Operational Resource Requirements

A computer program that can be run on a personal computer is available for performing the calculations. Large toxicity data bases exist for plant and animal species which can be used by this method. However, the range of required species which have been tested with each chemical restricts the number of chemicals for which an acute and chronic criterion can be calculated. The level of effort is low, particularly if the computer program is available. However, validation of literature reports requires a high level of expertise.

3.1.4 Summary

The guidelines were developed to calculate water quality criteria that will be protective of populations of most aquatic organisms. The guidelines are not concerned with what effects, if any, will occur in the ecosystem if concentrations reach or exceed the benchmarks. Criteria are developed for both acute and chronic exposure scenarios. The acute criterion is a prediction of a concentration threshold above which acute toxicity to some species might occur. It is derived primarily from laboratory acute toxicity data. The chronic benchmark can be derived from one of three data sets. No weighting is given to the quality or quantity of data within each data set. The lowest of the three chronic values (i.e., animal, plant, and tissue residue values) is chosen arbitrarily, even though the calculation schemes are different. The calculation schemes themselves are straightforward. However, validation of input data requires a high level of expertise in the area of aquatic toxicology.

Strengths of the approach are its wide applicability and rigor in requiring a minimal set of data to calculate a criterion. Limitations are that community or ecosystem effects are not directly assessed and that guidelines have not yet been established for chemical mixtures.

3.2 AN APPROACH TO ASSESSING EXPOSURE TO AND RISK OF ENVIRONMENTAL POLLUTANTS (EPA/OWRS 1983)

3.2.1 Introduction

A.D. Little, Inc. prepared this document for the Office of Water Regulations and Standards (OWRS) to provide guidelines for conducting risk assessments for waterborne pollutants and to identify priorities for further development. Part of the guidelines presented are for assessment of risks to non-human biota. A schematic diagram of the proposed approach to risk assessment is shown in Figure C3-1. The approach is qualitative. The result of the assessment is a listing or summary of species, locations, exposures, and effects levels, indicating the combinations most likely to result in high risks.

3.2.2 Description of Method

Receptor Characterization

Emphasis is placed on aquatic organisms, although the procedure is intended to be used to assess risks to any organisms coming in contact with water (e.g., waterfowl). The guidelines suggest that the assessor identify specific communities or species exposed or potentially exposed to the pollutant. Representative sensitive species should be identified and their ranges delineated. In addition, behavior patterns (i.e., migration, age structure) that might increase or decrease the potential for exposure should be described.

Hazard Assessment

The proposed hazard assessment is based on a literature review. Because the procedures are intended to be used for the priority pollutants, it is assumed that Ambient Water Quality Criteria will be available. The result of the hazard assessment is a tabulation of effects by species affected (e.g., fish, aquatic invertebrates) and by type of effect (e.g., lethal and sublethal). No methods for extrapolation between species or time frames are suggested. When available, the relationship between toxicity modifying factors and effects should be included in the summary.

Exposure Assessment

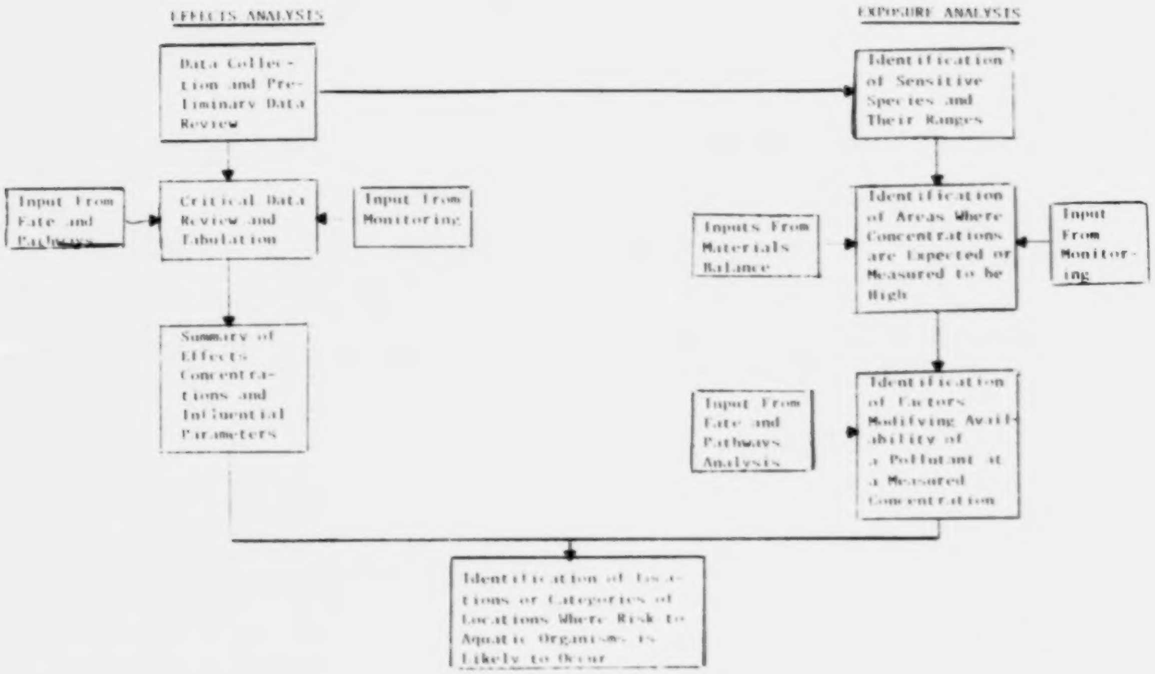
Potential for exposure is estimated using either environmental fate and transport models or field monitoring. Exposure analysis components include identification of the concentration of the chemical, the areal extent of contamination, and temporal variation in levels of contamination.

Risk Characterization

It is assumed that incomplete data will necessitate qualitative environmental assessments the majority of the time. An initial assessment is made to determine whether the chemical is likely to have (1) no effect on

FIGURE C3-1

SCHEMATIC DIAGRAM OF EPA/OWRS (1983)
APPROACH TO RISK ASSESSMENT


EFFECTS ANALYSIS
EXPOSURE ANALYSIS
Data Collection and Preliminary Data Review
Identification of Sensitive Species and Their Ranges
Input From Fate and Pathways
Critical Data Review and Tabulation
Input From Monitoring
Inputs From Materials Balance
Identification of Areas Where Concentrations are Expected or Measured to be High
Input From Monitoring
Summary of Effects Concentrations and Influential Parameters
Input From Fate and Pathways Analysis
Identification of Factors Modifying Availability of a Pollutant at a Measured Concentration
Identification of Locations or Categories of Locations Where Risk to Aquatic Organisms is Likely to Occur

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aquatic organisms; (2) some effects on certain sensitive species; (3) effects on most species; or (4) effects on all species. Exposure and hazard information is then examined to refine the rough analysis. Possible refinements include comparing time-dependent patterns of contamination levels (e.g., persistence, seasonal fluctuations) with species activity patterns and considering toxicity modifying factors such as hardness. Expected results can be validated with information on fish kills or field sampling programs. The goal of the assessment is to establish "key intersections" between exposure and effects data with regard to specific species and geographic locations. The product of the analysis is a listing or summary of species, locations, exposures, and effects levels, with an indication of the combinations most likely to result in high risks.

3.2.3 Operational Resource Requirements

The approaches proposed in this document can be made more sophisticated or simple, depending on needs and resources. If collection of field data is necessary, resource needs will be high. Although the approach is simple and qualitative, it requires a high level of judgment and knowledge of aquatic systems.

3.2.4 Summary

The guidelines presented in this document offer a systematic way to consider available data and design needs for possible field work. The strengths of the approach are that it is very flexible and relies on common sense and professional judgment. The limitations of the approach are that the results are not quantified. In addition, little guidance is provided on the approaches for extrapolating from available data to species and effects of concern, and the specific criteria upon which to base conclusions (e.g., NOEL, LC_{50}) are not defined.

3.3 PERMIT WRITER'S GUIDE TO WATER QUALITY-BASED PERMITTING FOR TOXIC POLLUTANTS / TECHNICAL SUPPORT DOCUMENT FOR WATER QUALITY-BASED TOXICS CONTROL

3.3.1 Introduction

Both the Clean Water Act and promulgated Federal regulations require that all National Pollutant Discharge Elimination System (NPDES) permits include limitations to achieve all applicable state water quality standards. All states have numerical standards for some individual toxicants, as well as narrative standards for pollutants. One of the most common narrative standards is that a state's waters shall be free from substances in concentrations or combinations toxic to humans, wildlife, or aquatic life. This standard can be used to limit both individual toxicants and whole effluent toxicity. The Permit Writer's Guide to Water Quality-Based Permitting for Toxic Pollutants (EPA/OWRS 1987) provides procedural recommendations to state and Federal NPDES permit writers. The Technical Support Document (TSD) for Water Quality-Based Toxics Control (EPA/OWRS 1985) provides additional guidance and explanation of the two basic approaches to water quality-based toxics control: the whole-effluent approach and the chemical-specific approach. Either or both approaches can be used for setting effluent limits or monitoring compliance. This review describes only the approaches recommended to ensure that state waters are free from substances toxic to aquatic life.

The whole-effluent approach to toxics control involves toxicity testing of the effluent. The measure of whole-effluent toxicity, information on mixing zones, and design flow of the receiving waters are then used to estimate a wasteload allocation/total maximum daily load (WLA/TMDL) for effluent discharge. The chemical-specific approach involves use of a water quality criterion (e.g., state numerical water quality criteria which are often derived from EPA ambient water quality criteria) and exposure modeling to establish an effluent discharge limit.

3.3.2 Description of Method

Receptor Characterization

The initial step in the water quality-based approach to toxic effluent control is determining the level of water quality that must be maintained to allow continuation of the state-designated use of the water body (e.g., cold water fishery). Further receptor characterization depends on whether the whole-effluent approach or the chemical-specific approach is employed. If the whole-effluent approach is followed, the TSD recommends use of three different test species so that a species sensitive to the toxicants in the effluent is likely to be tested. If the chemical-specific approach is followed, the receptor characterization is that associated with the development of the numerical criteria (see review of EPA/OWRS 1986 Ambient Water Quality Criteria methodology).

For the whole-effluent approach, it is not possible to predict a priori which species is likely to be most sensitive because different species exhibit different sensitivities to toxicants (e.g., trout are very sensitive to oxygen depletion but are relatively insensitive to certain toxicants). An analysis of species sensitivity ranges (as identified in the EPA Ambient Water Quality Criteria documents) indicated that if tests are conducted on three particular species (*Daphnia magna*, *Pimephales promelas*, and *Lepomis macrochirus*), the most sensitive of the three will exhibit an LC_{50} value within one order of magnitude of the most sensitive of all species tested. If fewer than three species are tested, a safety factor of 10 should be applied to the lowest observed LC_{50} value to extrapolate to more sensitive species. The TSD recommends against using resident species for the whole-effluent toxicity tests unless it is required by state statute or some other binding factor. The reason is that testing of resident species is more costly, more difficult, and subject to more variability than testing of standard laboratory species.

Hazard Assessment

The hazard assessment of the water quality-based approach to toxics control depends on whether the whole-effluent approach or the chemical-specific approach is followed. For the whole-effluent approach, toxicity tests are conducted on three test species using a series of dilutions of the whole-effluent. For the chemical-specific approach, the hazard assessment has already been conducted in the establishment of numerical ambient water quality criteria (see review of EPA/OWRS 1986 Ambient Water Quality Criteria methodology).

For the whole-effluent approach, an effluent sample is collected and diluted in test chambers; the dilutions are usually 100%, 30%, 10%, 3%, 1%, and a control. The receiving water is frequently used to dilute the effluent because it more closely simulates the effluent/receiving water interactions. The required measures of effluent toxicity are the LC_{50} (the effluent concentration expressed as the dilution at which 50% of the test organisms are killed) and the no-observed-effect-level (NOEL; the highest effluent concentration at which no unacceptable effect will occur even following continuous exposure). Because of the inverse relationship between toxicity and the reference concentration (e.g., the lower the LC_{50} or the NOEL, the higher the toxicity of the effluent), concentration-based toxicity measurements are translated into acute (TUa) or chronic (TUc) "toxic units." The toxic unit is simply 100 divided by the toxicity measure:

$$TUa = \frac{100}{LC_{50}} \qquad TUc = \frac{100}{NOEL}$$

where the LC_{50} or NOEL is expressed as percent effluent in the dilution water. Thus, an effluent for which the 10% dilution killed 50 percent of the test organisms is an effluent containing 10 TUa. An effluent contains 20 TUc if the highest concentration that did not produce adverse effects over a long exposure period was a 5% dilution.

Exposure Assessment

Some States have numeric criteria for whole effluent toxicity, often stated as end-of-the-pipe acute toxicity limits, that do not depend on an exposure assessment. Otherwise, effluent concentrations in both the mixing zone(s) surrounding the effluent discharge and in the remainder of the receiving water body must be estimated on the basis of the design flow of the receiving waters. Design flow is a hydrological condition which describes a low flow of a flowing water body and is calculated from the historical flow record. The level of effluent control is to be set on a "worst case" exposure scenario to protect aquatic life during low flow conditions, when the dilution potential of the receiving water body is lowest. Design flows can be calculated using an EPA recommended computer simulation program (DFLOW) or other methods. The goal of the exposure assessment is to determine the lowest flow expected for a specified period of time with a specified frequency of occurrence for comparison with the reference toxic units. The lowest flow averaged over any consecutive 7 day period that is expected to occur in a typical 10 year period (7Q10) is the recommended design flow for calculating dilution for the chronic ambient water quality criterion or for the whole-effluent identified NOEL. The lowest flow averaged over any 1 day period that is expected to occur in a typical 10 year period (1Q10) is the recommended design flow for calculating dilution for the acute criterion or the whole-effluent LC_{50} value.

Risk Characterization

Many state standards allow a zone of mixing around the effluent discharge point in which less stringent ambient water quality criteria apply than in the remainder of the receiving water. EPA's policy on mixing zones, described in the 1983 Water Quality Standards Handbook, is that any mixing zone should be free from materials which cause acute toxicity to aquatic life. Acute toxicity is of concern for organisms passing through the mixing zone on a daily or seasonal basis. Both acute and chronic toxicity are of concern for the remainder of the receiving water body.

Tiered testing, similar to that used under the Toxic Substances Control Act (TSCA) when testing a new chemical product for potential hazard, is recommended to provide a cost-effective method of obtaining the necessary data for toxic effluent control. At the screening level, the goal is to separate situations in which impacts on aquatic systems are improbable from those in which impacts are possible or probable. Screening level considerations include the dilution potential of the receiving water, the type of industry, the type and volume of industrial input, any existing data on toxic constituents in the effluent, and any history of toxic impact on receiving waters or compliance problems. If, during the screening analysis, a case is identified wherein impacts on aquatic organisms are possible or likely, definitive data gathering is then required using either the whole-effluent approach or the chemical-specific approach, or both.

In the whole-effluent approach, the recommended acute criterion for the acute design flow (1Q10) is 0.3 TUa. The adjustment factor of approximately one-third is used to extrapolate from a 50 percent mortality level (LC_{50}) to a

1 percent mortality level (LC_1). The criterion can be applied at different locations in the receiving water depending on the dilution situation. The recommended chronic criterion for the chronic design flow (7Q10) is 1 TUc. The waste load allocation (WLA) requirement is calculated on the basis of the toxicity criterion and the dilution factor based on the receiving water design flow as well as the effluent design flow. A separate WLA is calculated for the acute and chronic exposure scenarios, and an effluent performance level that will meet each WLA requirement is back-calculated. Permit limits are derived from the more restrictive performance level (the acute or the chronic design flow).

3.3.3 Operational Resource Requirements

The effort and cost of following the recommended analysis and testing procedures for NPDES permitting depends on the results of the dilution screening analysis. The TDS identifies five levels of dilution potential in the receiving water body and recommends increasing numbers of toxicity tests as the dilution potential of the receiving water declines. Potentially, both acute and short-term chronic toxicity tests might be required for three species. Compliance monitoring might also require effluent toxicity testing on a monthly basis with the one species determined to be most sensitive to the effluent.

3.3.4 Summary

The Water Quality-Based Toxics Control methodology includes two approaches to defining limits to toxic effluent discharges into surface waters. The whole-effluent approach involves determining the toxicity of the effluent mixture using bioassays with three species of aquatic organisms. The chemical-specific method involves the application of state water quality criteria for the designated uses of the receiving water. Each approach has advantages and disadvantages and is complementary to the other. EPA recommends using both approaches, as appropriate, to a given permitting situation.

The principal advantages of the whole-effluent approach compared with the chemical-specific approach are (1) the combined toxicity of all constituents in a complex effluent is measured, (2) the bioavailability of the toxic constituents is assessed, and (3) the effects of synergistic or antagonistic interactions of the effluent constituents are accounted for.

The principal disadvantages of the whole-effluent approach compared with the chemical-specific approach are (1) treatment systems are more easily designed to meet chemical-specific requirements, (2) engineers and permit writers are more familiar with chemical-specific approaches, (3) properties of specific chemicals in complex effluents (e.g., bioaccumulation) are not assessed.

3.4 BIOLOGICAL CRITERIA FOR THE PROTECTION OF AQUATIC LIFE

3.4.1 Introduction

Since 1980, Ohio EPA has been conducting biological evaluations of state surface water quality to quantify the attainment or non-attainment of state designated surface water uses. Field measurements of the fish and macroinvertebrate sub-communities are used to calculate three indices of biological integrity: (1) Index of Biotic Integrity (IBI, based on the fish sub-community), (2) Modified Index of Well-Being (Iwb, also based on fish), and (3) Invertebrate Community Index (ICI, based on the macroinvertebrate sub-community). Ohio EPA uses the three indices in conjunction with chemical-specific ambient water quality criteria and toxicity testing for discharge permitting to improve and maintain the biological integrity of the state's surface waters (Ohio EPA 1987a, 1987b, 1988).

Ohio EPA has found the indices to meet several important criteria. The indices depend on actual biological measures, rather than surrogate measures such as contaminant concentration. The measures indicate effects at several trophic levels. The response ranges of the indices are suitable for the regulatory needs. The indices are sensitive to the environmental conditions of interest. The indices are reproducible and precise within defined and acceptable limits. Finally, the signal-to-noise ratio for the combination of the three indices is high.

3.4.2 Description of Method

Receptor Characterization

The Ohio EPA definition of biological integrity depends on the biological conditions exhibited by the "least impacted" surface water habitats, rather than "pristine" habitats which would represent unattainable conditions over most of the state. Ohio EPA uses an ecoregion approach to identify reference aquatic communities, relying on Omernik's (1987) classification of aquatic ecoregions of the United States from maps of land-surface form, soils, potential natural vegetation, and land use. Within each of the five ecoregions, three types of rivers/stream habitats are defined based on size and water flow: wading sites, boat sites, and headwater sites.

The fish and macroinvertebrate sub-communities were selected for evaluation of surface water quality because there is sufficient information concerning their life-histories, distribution, and tolerances and also because these sub-communities are dependent upon the other sub-communities (e.g., plants, microinvertebrates) for their well-being. The fish sub-community is the most conspicuous and is generally of concern for its commercial or sport value.

The Index of Biotic Integrity (IBI) incorporates 12 different metrics of the fish sub-community to derive a final IBI score. The value of each individual metric measured at an evaluation site is compared with the value expected on the basis of the analysis of "least impacted" reference sites in the same ecoregion with the same water flow characteristics. Ratings of 5, 3, or 1 are assigned to each of the 12 metrics based on whether the evaluation site value approximates, deviates somewhat from, or deviates strongly from the expected value, respectively. Expected values are derived from the data collected at the "least impacted" reference sites. The 12 community metrics were modified from those proposed by Karr (1981) to include measurements that could be reliably made given the sampling gear required for each stream size. The IBI metrics include the total number of species, three metrics related to the total number of species of a specified type of fish (e.g., sucker, minnow, sunfish), the number sensitive (i.e., intolerant) species, the percent tolerant species, the percent omnivorous species, the percent insectivorous species, the percent top carnivore or pioneering species, the total number of individuals, the percent hybrids, and the percent diseased individuals or fish exhibiting deformities, eroded fins, lesions, or external tumors.

The Index of Well-Being (Iwb) for the fish sub-community incorporates four indices: numbers of individuals, biomass, the Shannon diversity index based on number, and the Shannon diversity index based on weight. Number and biomass data are obtained from pulsed D.C. electrofishing catches, where sampling effort is normalized on the basis of distance. Ohio EPA recently developed a modification of the Iwb that makes the index more sensitive to environmental disturbances. In the modified Iwb, any of 13 highly tolerant species, hybrids, or exotic species are eliminated from the numbers and biomass components of the Iwb but still included in the two Shannon diversity indices. Ratings are assigned to each of the four indices on the basis of similarity to the reference sites.

The Invertebrate Community Index (ICI) is an index of the macroinvertebrate sub-community as measured on artificial substrates introduced into the surface water for a specified period of time. The ICI is a modification of the IBI for fish and consists of 10 metrics, including the total number of taxa, number of mayfly taxa, number of caddisfly taxa, number of dipteran taxa, percent mayflies, percent caddisflies, percent midges (tribe tanytarsini), and percent tolerant organisms. Mayflies, caddisflies, and tanytarsinid midges are important components of undisturbed stream macroinvertebrate sub-communities that range from highly to moderately sensitive to pollutant stress. Ratings are assigned to each of the 10 metrics on the basis of similarity to the reference sites.

Regional criteria for the IBI, modified, Iwb, and ICI were established on the basis of the measurements of each metric from the reference sites. Ecoregional criteria for the warmwater habitat (WWH) use designation were established as the 25th percentile value from the reference site values for each ecoregion. The exceptional warmwater habitat (EWH) use designation criteria were set at the 75th percentile value. The 25th percentile for the WWH use designation was chosen to compensate for the inclusion of marginal sites in the original reference site data base. Ecoregional criteria for coldwater habitats, however, have not yet been developed.

Hazard Assessment

A hazard assessment is not part of the biological criteria methodology. However, the biological criteria are intended for use in conjunction with chemical identification, chemical criteria, and toxicity testing to assist water quality management decisions.

Exposure Assessment

Exposure characterization is not part of the biological criteria methodology. The fish and macroinvertebrate sub-communities represent relatively long-lived organisms that have integrated the effects of continuous exposure to the pollutant and other stressors over a period of years.

Risk Characterization

The biological indices from an evaluation site can be used in several ways. The indices can be compared with the criteria values for the ecoregion to establish the attainment or non-attainment of a designated use. The indices for upstream and downstream locations can be compared to help identify a hazardous discharge. Indices from the same site can be followed over time to measure the effectiveness of a regulatory control. For some types of pollutants, the ICI measure of the macroinvertebrate sub-community is a more sensitive indicator than either fish index, and for other types of stress, the fish sub-community indices can be more sensitive. All three indices are therefore used to indicate the quality of Ohio surface waters. Figure C3-2 illustrates how the three indices have been used to illustrate the general improvement in water quality over the last 10 years at selected sampling stations in the state of Ohio. Figure C3-3 illustrates how the indices can be used to document environmental degradation associated with one or more point sources of pollutant stress with distance along a river.

3.4.3 Operational Resource Requirements

Ohio EPA provided a cost comparison of fish sub-community and macroinvertebrate sub-community evaluations of water quality with chemical and physical sampling of surface water and acute and acute/chronic bioassay tests on effluents of the type used for National Pollutant Discharge Elimination system (NPDES) permitting. While chemical/physical sampling (4-6 samples per site) costs between $1,500 and $1,700, and bioassays can run from $3,200 for a screening level assay to $8,000 - $12,000 for a 7-day bioassay, a macroinvertebrate evaluation typically costs $700 and fish community sampling costs Ohio EPA between $670 and $900 (2 to 3 passes per site). Thus, the biological evaluation methodology is cost competitive with the more commonly used measures of surface water quality. The initial development of Biological Criteria, however, required a substantial effort in sampling a large number of "least impacted" reference sites.

FIGURE C3-2

BIOLOGICAL INDICES OF SURFACE WATER QUALITY IN THE SCIOTO RIVER

(Source: Ohio EPA 1988)

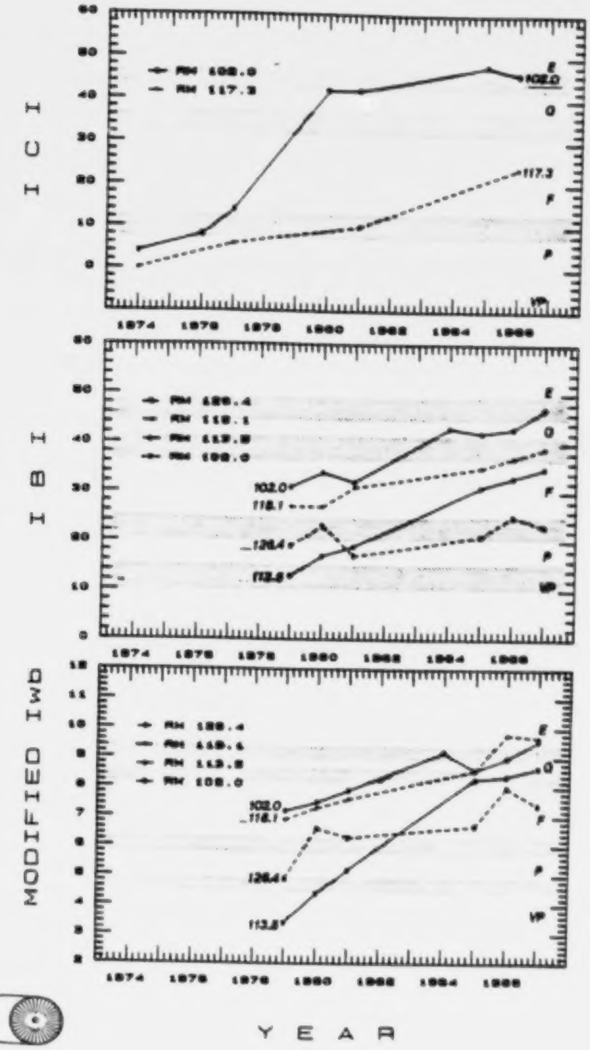

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Figure C3-2. Results of the Invertebrate Community Index (ICI), Index of Biotic Integrity (IBI), and Modified Index of Well-being (Iwb) at selected sampling locations in the middle Scioto River between 1974 and 1987. Shading indicates boundaries between exceptional (EWH), good (WWH), fair, poor, and very poor conditions and the variability of each index. Sampling was conducted during July-October of each year.

FIGURE C3-3

LONGITUDINAL TRENDS IN BIOLOGICAL INDICES OF SURFACE WATER QUALITY IN THE CUYAHOGA RIVER

(Source: Ohio EPA 1988)

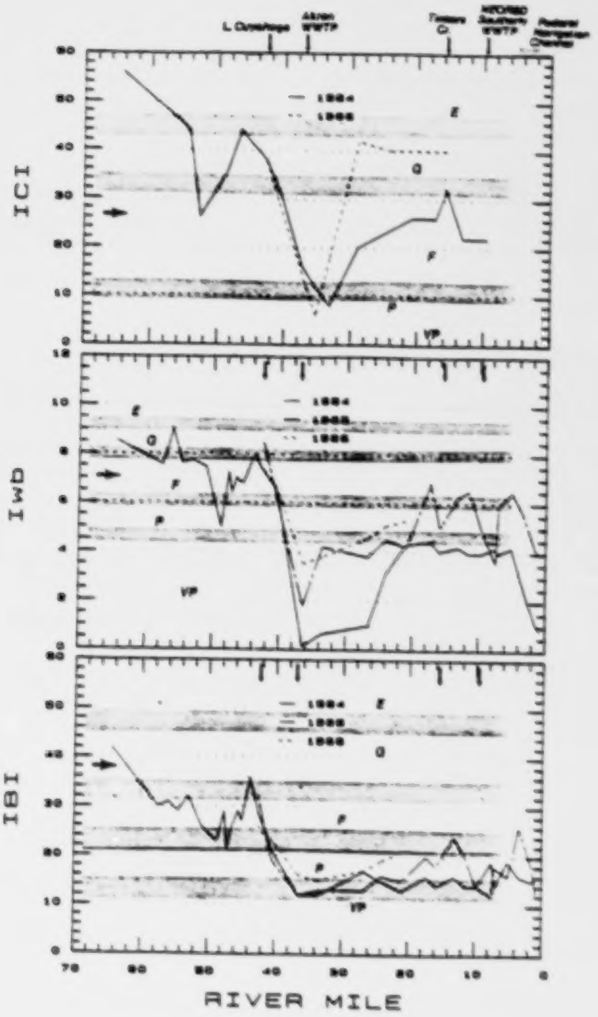

Figure C3-3. Longitudinal trend of the Invertebrate Community Index (1984, 1986) and Modified Index of Well-Being (fish; 1984, 1985, and 1986) in the Cuyahoga River study area. Shading indicates boundaries between exceptional (EWH), good (WWH), fair, poor, and very poor conditions and the variability of each index. Sampling was conducted during June-September of each year. Horizontal arrow indicates direction of flow; environmental influences are indicated at the top.

3.4.4 Summary

Ohio EPA has developed and is using three indices of biological integrity to measure attainment of the goals of the Water Quality Act (WQA). Unlike chemical criteria which serve as surrogate measures of the attainment of the biological goals of the WQA or effluent toxicity testing to control chemicaldischarges, the indices incorporate direct measurements of the structure of biological communities, representing a top-down approach. There are several advantages to using measurements of the fish and invertebrate communities to assess water quality. One advantage is that the organisms have been exposed continuously to the actual conditions and history of pollutant stresses in the receiving waters. Extrapolation between responses of organisms in the laboratory and responses of organisms in the field are not required. In addition, stressors other than toxic substances for which laboratory data are available can be detected. The organisms integrate exposure over time and space, and the condition of the resident community is the result of the full history of environmental conditions, including both common and extreme events.

Some difficulties that have discouraged the development of biological criteria and community-level indices in the past have been overcome through standardization of field sampling methods, acceptance of several types of measures as indicative of biological integrity, calibration of indices on the basis of ecoregion and surface water body type, and measurement of the indices for a large number of reference sites. Over the past 10 years, Ohio EPA has found that the signal-to-noise ratio and reproducibility of the indices are sufficiently high to provide useful indications of changes in the biological community in response to pollutants or other stresses.

3.4.5 References

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3.5 NIAGARA RIVER BIOTA CONTAMINATION PROJECT: FISH FLESH CRITERIA FOR PISCIVOROUS WILDLIFE (NYS/DEC 1987)

3.5.1 Introduction

To interpret the results of the Niagara River fish tissue monitoring program, the Niagara River Toxics Committee (NRTC 1984) of New York State recommended that residue criteria be established, if none were available, for the chemicals that had been detected. The two primary objectives of this report were (1) to develop fish flesh criteria for 19 organochlorine chemicals that will protect piscivorous wildlife, and (2) to evaluate a methodology for deriving such criteria where toxicology data are unavailable for wildlife species of concern. In the past, fish flesh criteria for the protection of wildlife generally have been derived from wildlife feeding studies, of which few are available. The NYS/DEC approach is to use the extensive laboratory animal toxicology data base employed for the derivation of human health criteria to extrapolate to wildlife species. In the following sections, we review this methodology for deriving fish flesh residue criteria.

3.5.2 Description of Method

Receptor Characterization

A list of 18 species of piscivorous wildlife which are current or former inhabitants of the Niagara River valley were selected as the ecological targets of concern. For each of these species, body weight, daily food consumption by weight, and food habits were determined. From these data, the mammal and bird with the greatest ratios of daily food consumption to body weight were selected for use in calculation of fish flesh criteria. Mink, with an average body weight of 1 kg and daily food consumption of 0.15 kg/day, were selected as the representative mammalian target. Because several species of birds consume an amount of food equal to about 20 percent of their body weight daily, a "generic" bird was selected with a weight of 1 kg and a daily food consumption of 0.2 kg.

Hazard Assessment

The results of laboratory animal feeding experiments are extrapolated to fish flesh criteria for wildlife using the following general formula:

$$\left[\frac{\text{Toxicity Value (mg/kg-day)} \times \text{Uncertainty Factor} \times \text{Target Species Weight (kg)}}{\text{Target Species Daily Intake (kg/day)}}\right]$$

The Toxicity Value is either a no-observed-effect-level (NOEL), lowest-observed-effect-level (LOEL), or cancer risk-based dose corresponding to a 1/100 risk of cancer. Where a chronic NOEL for a sensitive species is unavailable, the uncertainty factor is applied as follows:

0.1 is used to estimate a chronic NOEL from subacute data;

0.2 is used to estimate a chronic NOEL from a chronic LOEL; and

0.1 represents the interspecies uncertainty factor to use when chronic data are available from only one or two species in the same class.

Only laboratory data from mammalian species are used to extrapolate to a mammalian wildlife species (i.e., mink), and only laboratory data from birds are used to extrapolate to a wildlife bird species (i.e., the "generic" bird).

Toxicity endpoints of concern included mortality, body weight gain, liver and kidney weight (as a percentage of body weight), liver and kidney micropathology, and reproductive losses. The interspecies uncertainty factor is based on a literature review that supports a 10-fold or more range in sensitivity of species to thoroughly tested organochlorines. The factor of 0.1 was selected to estimate a chronic NOEL from subacute data on the basis of a review by Weil and McCollister (1963) in which the authors found that a 10-fold factor would cover 95 percent of the chemicals tested for short-term (e.g., 30 to 90 days) versus long-term (e.g., two years or lifetime) exposure. Weil and McCollister (1963) also presented data that justified using a factor of 0.2 to extrapolate from a LOEL to a NOEL (all ratios of LOEL/NOEL were 10 or less, and 92 percent were 5 or less). The NYS/DEC also recommends using supplementary data when available, such as epidemiological field studies.

As one method of validating this approach, NYS/DEC compared the fish flesh residue criteria developed for five chemicals, using the method outlined above including the uncertainty factors, with toxicity data for the actual target wildlife species of concern. For PCBs, DDT, aldrin/dieldrin, and mirex, but not endrin, at least one of the lab species-based non-carcinogenic criteria was lower than target species criteria. In the case of endrin, the mallard exhibits a very high sensitivity to the chemical. Thus, using laboratory animal data in conjuction with uncertainty factors should result in fish residue levels that would usually be protective of wildlife species. This method does not, however, address the possible additive or synergistic effects of mixtures of similar compounds or the susceptibility of wildlife *in nature* to toxic substances.

Exposure Assessment

The most sensitive bird (i.e., "generic") and mammal (i.e., mink) species are assumed to consume a diet consisting of 100 percent fish. The NYS/DEC points out that biomagnification of contaminants might continue in the terrestrial food chain, such as when eagles consume gulls that have consumed contaminated fish. The method for deriving fish flesh criteria outlined above is not protective of terrestrial animals in higher trophic positions than the piscivorous target wildlife species.

Risk Characterization

To assess risk to wildlife fish consumers near the Niagara River, the fish flesh criteria were compared to residues in Niagara River fish (e.g., spottail shiners, alewives, smelt, coho salmon) by the quotient method (see Review 7.1.1). Extrapolations of residue levels in spottail shiners (which were the only species sampled on a regular basis over the years) to residue levels in other fish species were accomplished by assuming that all of the organochlorine compounds were sequestered in the lipid portion of the fish, and using a relative lipid content correction factor. The selection of a 1/100 cancer risk level as an acceptable cancer risk for wildlife was a preliminary decision and will be studied further.

3.5.3 Operational Resource Requirements

The methodology for setting fish flesh residue criteria is simple and easy to follow. Large toxicity data bases exist for mammalian laboratory species because these data are used to assess human toxicity. Fewer data are available for laboratory bird species for compounds other than pesticides.

3.5.4 Summary

The guidelines developed to calculate fish flesh residue criteria allow extrapolation from a large laboratory animal toxicity data base to fill a large data gap in available wildlife long-term feeding studies. The guidelines might not be sufficiently protective of wildlife species that consume piscivorous wildlife species, however. The guidelines are not concerned with what effects, if any, will occur in the ecosystem if concentrations reach or exceed the benchmarks. Nor does the risk assessment portion address the problem of exposure to multiple contaminants. Criteria are developed only for chronic dietary exposure scenarios. The calculation schemes themselves are straightforward. However, validation of input data requires a high level of expertise in the area of aquatic toxicology.

Strengths of the approach are its wide applicability and apparent validity. Limitations are that community or ecosystem effects are not directly assessed, that guidelines have not yet been established for chemical mixtures, and that validation efforts have thus far been limited.

Fish residue criteria developed using this methodology could be used in conjunction with bioaccumulation factors to adjust chronic water qualtity criteria for substances with a strong tendency to bioconcentrate.

3.5.5 References

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4.0 METHODS/ASSESSMENTS DEVELOPED UNDER FIFRA

4.1 STANDARD EVALUATION PROCEDURE FOR ECOLOGICAL RISK ASSESSMENT (EPA/OPP 1986)

4.1.1 Introduction

The Office of Pesticide Programs (OPP) has developed a Standard Evaluation Procedure for carrying out ecological risk assessments to evaluate environmental toxicology and effects data submitted in support of pesticide registration. The approach is a modified quotient method in which estimated environmental concentrations (EECs) are compared to environmental toxicity endpoints; the resulting ratios are evaluated according to regulatory risk criteria (RRCs) established by regulation or, in the case of endangered species, by a Memorandum of Understanding between EPA and DOI.

OPP developed this approach because of several features unique to the ecological risk evaluation of pesticides. Since pesticides are used by deliberate and broadscale introduction into the environment, and since pesticides are by definition toxic to at least some component of the biosphere, a basic set of environmental test data is required for all pesticides before use is allowed. The approach is designed to identify pesticides with high potential for ecological impacts, based on acute toxicity, which would then require further testing and refinement of the risk assessment. Finally, separate regulatory risk criteria are used to make regulatory decisions when endangered species are the receptors of concern.

4.1.2 Description of Method

Receptor Characterization

Both aquatic and terrestrial receptors are considered under this method. Assessments are focused at the population level, although the value of individual members of endangered species is considered by using a more stringent RRC. Life habit characteristics are considered when characterizing potential receptors. For example, potential aquatic receptors are identified and differentiated based upon the habitat in which they exist (cold or warm water, salt or fresh water). Terrestrial species are identified and characterized based upon habitat and dietary characteristics. Indicator species that most closely represent the characteristics of potential non-target receptors are selected for the risk assessment. Seasonal or life-cycle characteristics and the geographic location of the potential receptors are not considered.

Hazard Assessment

Hazard assessments are conducted at the population level, and acute and chronic toxicity are the endpoints considered; dose-response data and community and ecosystem responses are not evaluated. In addition, the influence of potential toxicity modifying factors (e.g., pH, hardness, behavioral modifications) is not considered.

Toxicity tests that may be required for assessment are shown in Table C4-1. The tests are arranged in a tiered system which progresses from basic laboratory tests to applied field tests. In general, the first tier consists of tests to determine acute endpoints (e.g., LC_{50}s) using common laboratory organisms; the second tier consists of tests for sublethal effects or tests on specific organisms; and the third tier includes field tests. The results of each tier of tests are evaluated to determine the potential of the pesticide to cause adverse effects and to determine whether further testing is needed.

Exposure Assessment

The exposure assessment is also conducted in a tiered manner. In the lower tiers, environmental exposure concentrations (EECs) can be estimated using modeling, whereas field monitoring data may be required for the highest tier. In the lower tiers, EECs are determined based on fate and transport data (for aquatic systems) and residue chemistry and monitoring data (for terrestrial systems), as well as the rate, frequency, timing, and method of pesticide application. Exposure pathways are via water (for aquatic species) and via food (vegetation and nontarget insects) for terrestrial species. EECs in aquatic systems are estimated using hydrologic computer models developed by EPA (EXAMS and SWRRB). These models estimate minimum and maximum concentrations over time.

EECs for the first tier in terrestrial systems are derived using pesticide residue profiles based upon published monitoring data. This method uses the maximum and mean estimates of pesticide concentration immediately following application. Different estimates of residue concentrations are derived for different types of vegetation and nontarget insects. The residue estimates are the EEC and are developed for those types of vegetation and insects believed to comprise the diet of the nontarget species. EECs are compared to RRCs derived from dietary concentration dose-response data. If only dosage data are available, these values are converted into dietary concentration values using assumed body weight and food intake values for the nontarget species.

Risk Characterization

Risks are estimated by comparing the EEC to a set of regulatory risk criteria (RRC). The RRCs for acute toxicity are equal to the LC_{50} or LD_{50} divided by a safety factor of either 5, 10, or 20. The safety factors were derived by examining a cross-section of existing acute lethality dose-response data and determining the fraction of the median lethal value that corresponds to mortality in 0.1% of the population. (Mortality of 0.1% was regarded as sufficiently protective of a population.) For the typical (average) dose-response curve, a value one-fifth of the median lethal value corresponds to mortality in 0.1% of the population. Hence, a safety factor of five is applied to the acute toxicity value to derive an RRC. An additional safety factor of two is used for aquatic species because, it was reasoned, these species are less capable of limiting their exposure to contaminants through

TABLE C4-1

WILDLIFE AND AQUATIC ORGANISM DATA REQUIREMENTS

Avian and Mammalian Tests

- Avian single-dose oral LD_{50}
- Avian dietary LC_{50}
- Wild mammal toxicity
- Avian reproduction
- Simulated and actual field testing
- Honey bee: acute contact LD_{50}
- Honey bee: toxicity of foliar residues

Aquatic Organism Tests

- Freshwater fish acute toxicity
- Freshwater invertebrate acute toxicity
- Estuarine/marine organism acute toxicity
- Fish early life-stage study
- Aquatic invertebrate life-cycle study
- Aquatic organism bioconcentration
- Simulated or actual field testing

Source: 40 CFR 157.145 and EPA/OPP 1986.

food switching or by moving out of treated areas (e.g., ponds). Safety factors of 10 and 20 are used for terrestrial and aquatic endangered species, respectively. These higher safety factors are used for endangered species because even a single death in these species is considered to be of special concern. There is no safety factor applied to chronic no-effect-level toxicity values to account for the uncertainty associated with laboratory-to-field extrapolations.

If the EEC exceeds the RRC, a risk is presumed to exist and further testing may be required. The degree of risk is not addressed. Using this approach, potential risks to aquatic and terrestrial organisms following exposures to a single chemical via a single route of exposure are evaluated; multiple chemical exposures and multiple pathways are not considered, and, therefore potential antagonistic, synergistic, or potentiating interactions are not considered.

4.1.3 Operational Resource Requirements

The operational resource requirements of the Standard Evaluation Procedures approach should be low to moderate for chemicals for which toxicity information already exists. Operational resource requirements will be much higher for new chemicals for which testing will be required. The approach would be relatively simple to implement.

4.1.4 Summary

The Standard Evaluation Procedures for evaluating ecological risks proposed by EPA's Environmental Effects Branch is a quantitative risk evaluation approach. The primary advantages of this approach are that it is relatively simple to use. In the first tier assessment, it uses acute toxicity data that are readily available for many chemicals. In addition, this approach considers the characteristics of potential receptors when selecting indicator species and determining terrestrial exposures. To extrapolate to effects of chronic exposure from acute toxicity data, acute LD_{50} or LC_{50} values are divided by safety factors. A safety factor of 5 is used for acute data from birds and mammals, while a factor of 10 is used for aquatic organisms because they cannot avoid exposure as easily. An additional safety factor of 2 is applied if an endangered species might be at risk. No safety factor is applied to chronic no-effect-levels determined in the laboratory.

The Standard Evaluation Procedures, however, have several limitations. Many of these limitations are inherent weaknesses of the quotient method; others are unique to this method. Some of the major limitations of this approach are:

- The method does not compensate for differences between laboratory and field populations.
- It cannot be used for estimating indirect effects of toxicants, such as food chain bioaccumulation.

- It has unknown reliability (i.e., has not been validated) and does not quantify uncertainties.

- It does not account for other ecosystem effects (e.g., predator-prey relationships, community production/metabolism, structural shifts, etc.).

- It does not consider factors (biotic and abiotic) that might influence toxicity.

- Only one exposure pathway is considered for aquatic species and one for terrestrial species.

- Spatial variation in contaminant concentration is not considered.

- Multiple chemical exposures are not considered. While this is sufficient for evaluating the potential effects of application of a single pesticide, it would not be applicable for situations where concomitant exposure to more than one chemical might occur.

4.2 COMPUTER-BASED ENVIRONMENTAL EXPOSURE AND RISK ASSESSMENT METHODOLOGY FOR HAZARDOUS MATERIALS (CHEMICAL MIGRATION RISK ASSESSMENT; Onishi *et al*. 1982, 1985)

4.2.1 Introduction

The Chemical Migration Risk Assessment (CMRA) methodology has two stated objectives as described by Onishi *et al*. (1982): (1) to predict the occurrence and duration of pesticide concentrations in surface waters receiving runoff from agricultural lands, and (2) to develop a preliminary risk assessment procedure to predict the potential damage to aquatic biota. Although these were the stated purposes, the methodology can be used with little or no modification to evaluate the impact of any organic chemical which enters water from land.

The methodology is actually a series of models developed for EPA Athens Laboratory by Batelle Northwest which may be used in conjunction with other models developed by the U.S. Department of Agriculture or Nuclear Regulatory Commission. The algorithms have also been incorporated in the Center for Exposure Assessment Modeling (CEAM) - supported model HSPF (Hydrologic Simulation Program - FORTRAN). The basic architecture of the methodology is shown in Figure C4-1. Individual models from the methodology can be linked together in various fashions depending on the type of water body and dimensionality of the system. The methodology has been documented extensively (Table C4-2); however, the most important overview documents are Onishi *et al*. (1982 and 1985).

4.2.2 Description of Method

Receptor Characterization

The methodology is more hydrologically than biologically oriented and thus is weak in its receptor characterization components. It can consider freshwater, estuarine, or marine systems. Since the output is a probabilistic risk assessment, it can deal with both individual or population risks if the size of the population is known. The operator has considerable flexibility in choosing receptors and time frames. For example, risk to an early life stage (ELS) of a particular species could be assessed if toxicity data and sufficient information concerning the space-time location of the ELS were known.

Hazard Assessment

The model basically integrates acute (LC_{50}) and chronic (MATC) values into a time-dose-response curve. Only three endpoints, "safe", "mortality", and "sublethality" are used, although these could be expanded. No toxicity modifying factors are considered. Uncertainty is considered implicitly by using safety factors in developing MATCs or extrapolating between LC_{50} values obtained under different time frames. Many of the apparent problems with the hazard assessment component (e.g., failure to consider other endpoints or the

FIGURE C4-1

SCHEMATIC DIAGRAM OF THE CMRA METHODOLOGY
(Adapted from: Onishi _et_ _al_. 1985)

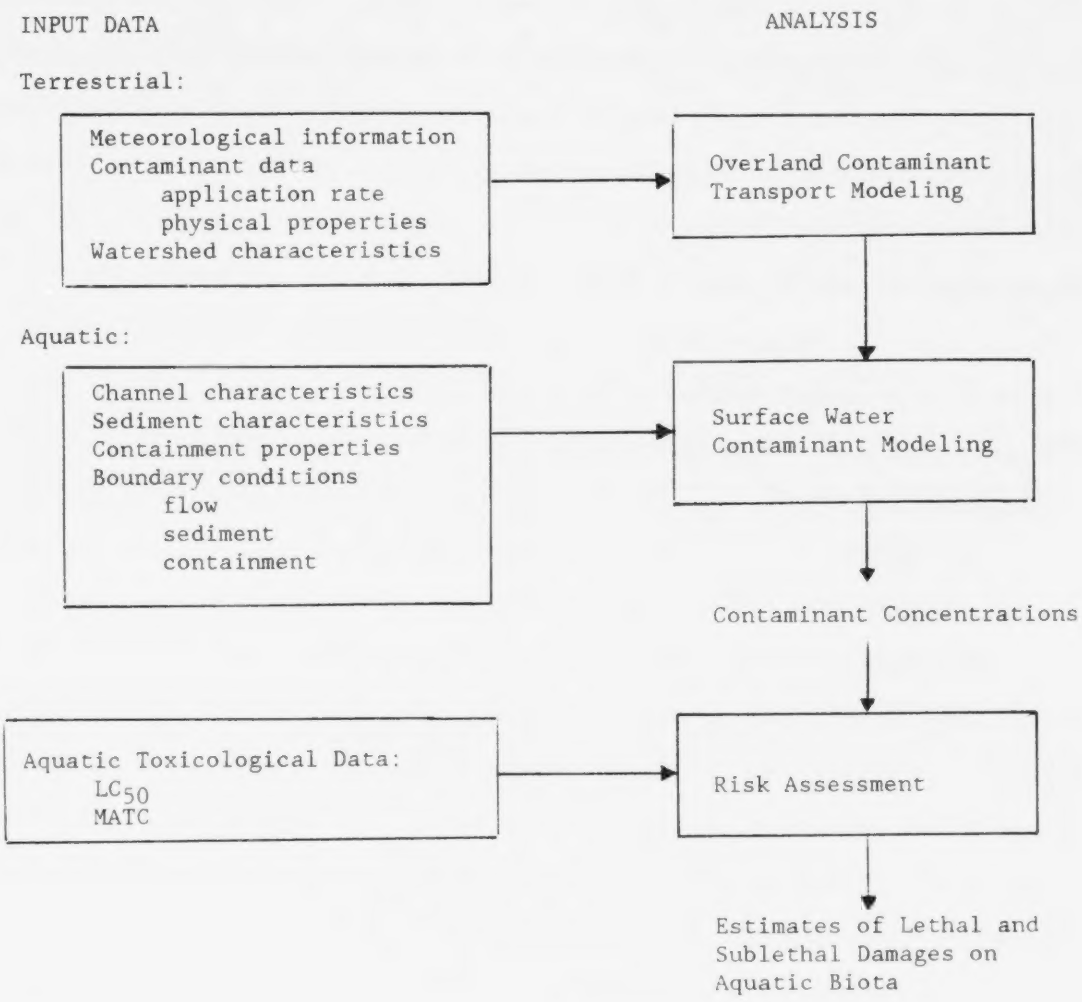
INPUT DATA
ANALYSIS
Terrestrial:
Meteorological information
Contaminant data
application rate
physical properties
Watershed characteristics
Overland Contaminant Transport Modeling
Aquatic:
Channel characteristics
Sediment characteristics
Containment properties
Boundary conditions
flow
sediment
containment
Surface Water Contaminant Modeling
Contaminant Concentrations
Aquatic Toxicological Data:
LC_{50}
MATC
Risk Assessment
Estimates of Lethal and Sublethal Damages on Aquatic Biota

TABLE C4-2

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Onishi, Y. and Wise, S.E. (1982) Mathematical Model, SERATRA, for Sediment Contaminant Transport in Rivers and its Application to Pesticide Transport in Four Mile and Wolf Creeks in Iowa. EPA-600/3-82-045.

Olsen, A.R. and Wise, S.E. (1982) Frequency Analysis of Pesticide Concentrations for Risk Assessment (FRANCO Model). EPA-600/3-82-044.

lack of inclusion of a true exposure-response curve) are not inherent in the methodology--given more data and users who are biologically oriented, several of the apparent problems could be overcome.

Exposure Assessment

The methodology excels at exposure assessment since many of the component models were developed specifically for this purpose. The user can select from a wide range of hydrologic solute transport models both in overland flow and in surface water. If the hydrodynamics are complex, it is relatively simple to link a hydrodynamic model with the rest of the methodology. The output is typically stochastic although it could be forced to be deterministic. In a typical application, this output is in the form of the probability of occurrence and duration of specific toxicant concentrations; thus there is a de facto consideration of uncertainty. The exposure component has been verified with two pesticides: toxaphene and Alachlor. Various models used in the exposure component have been validated by comparison of field results to predicted values; however, the entire component has not been validated. If required, the exposure models can be calibrated by manipulation of input variables.

Risk Characterization

CMRA uses probabilistic risk assessment to evaluate impacts on aquatic life. In this component, the model known as FRANCO takes the time-dependent output of the exposure models and calculates the number of times and fraction of the time that concentration-duration levels (e.g., 96 hour LC50) are exceeded. Risk is then calculated as the frequency of occurrence of an event (e.g., exceeding an MATC) and its consequences (e.g., mortality). Certain assumptions are used in applying this method, including: a 96 hour cutoff between acute and chronic; concentrations less than the MATC are "safe"; concentrations between the MATC and the concentration-duration curve result in "sublethality" or "damage"; and concentrations over the concentration-duration curve result in "mortality". If the size of the population is known, this leads to prediction of the number of effects. The probabilities shown on the output can also be interpreted as risk to an individual. If toxicological data on a chemical mixture are available, then the effect of the mixture can be assessed. As it stands, the methodology is limited to exposure through water. Food chain exposure is not considered.

4.2.3 Operational Resource Requirements

These depend on which of the overland transport and/or surface water solute transport models are selected. A mini/mainframe would be required to have the flexibility to use all model components. Since the methodology is most sophisticated with respect to exposure modeling, an experienced hydrologist probably would be required to run the models and interpret the results.

4.2.4 Summary

Both the overland transport and surface water solute transport components were developed independently of the risk assessment (FRANCO) component. The aquatic toxicology input is also independent. Therefore, use of the methodology should not be considered to be restricted to the models originally available (e.g., TODAM, SERATRA, FETRA, FLESCOT or Mixed Tank Models). The strongest component of the methodology is the FRANCO model, a probabilistic risk assessment which has considerably more utility and power than methodologies using quotients. It appears to be quite flexible and adaptable to terrestrial receptors, mixtures of toxicants, and even ecosystem effects given sufficient information. The overall methodology has been verified for two pesticides: toxaphene and Alachlor; it has not been validated, however. Although it presently considers as endpoints only "safe", "mortality", and "sublethality", it could be expanded to include such parameters as impacts on target organs or specific disease states if the toxicological data were available.

5.0 METHODS/ASSESSMENTS DEVELOPED UNDER RCRA

5.1 POTENTIAL FOR ENVIRONMENTAL DAMAGE: PROXIMITY OF MINE SITES TO SENSITIVE ENVIRONMENTS (EPA/OSW 1987a)

5.1.1 Introduction

ICF Incorporated has developed for EPA's Office of Solid Waste a qualitative approach for ecological assessment that is based on the proximity of sensitive environments to potential sources of contaminants. The approach is most appropriate for screening-level analysis, and has been used to preliminarily assess the potential for environmental impacts from oil and gas and mining activities.

The term sensitive environment refers to environmental areas that are either ecologically critical, unique, or vulnerable; are of particular cultural significance; or are set aside for the purpose of conservation. The assessment approach is based on the concept that actual or potential impacts to sensitive environments are generally of greater concern to society than comparable impacts in other environmental areas. Waste sources near sensitive environments are regarded as having a greater potential for environmental impact. Although the proximity of sensitive environments to waste sources is not an explicit criterion for determining ecological risk, it is an important consideration.

The approach is not a complete ecological risk assessment methodology because exposure and hazard assessments are not conducted. It does, however, provide potentially useful concepts for receptor characterization and risk determination.

5.1.2 Description of Method

Receptor Characterization

Four categories of sensitive environments were identified, encompassing both aquatic and terrestrial areas: endangered and threatened species habitats; wetlands; National forest system lands; and National park system lands. For any particular geographic area, sensitive environments can be identified using maps or available data bases. For example, information published by the U.S. Fish and Wildlife Service (USFWS) can be used to identify endangered and threatened species habitats. The USFWS has identified the historical ranges of approximately 400 endangered and threatened species and the critical habitats for 96 species. Also, the Nature Conservancy maintains a data base that can be used to identify endangered and threatened species habitats for any given location. Wetlands can be identified using U.S. Geological Survey 7.5 minute quadrangle maps or quadrangle maps published by the National Wetlands Inventory (USFWS). National forests and parks also can be located on quadrangle maps.

Risk Characterization

Under this assessment scheme, the degree of risk posed by any contaminant source is qualitatively assessed using the spatial relationship between the source and the receptor (sensitive environment). The potential for environmental damage increases as the distance to the sensitive environment decreases or as the number of proximate sensitive environments increases.

5.1.3 Operational Resource Requirements

This approach is based on information that is readily available for virtually all areas of the United States. The effort and costs for obtaining and interpreting the information are low.

5.1.4 Summary

This approach is an easily-implemented, low-cost, qualitative method for ranking the potential for waste sites to impose adverse impacts on valuable communities and portions of ecosystems. The potential for impacts is determined qualitatively based on the proximity of sensitive environments to a contaminant source. Because no absolute criteria relating distance to risk can be established without consideration of waste characteristics and exposure pathways, the approach is limited to use as a comparative screening analysis where several contaminant sources are being evaluated. The approach is not precise and has numerous other limitations (e.g., no hazard or exposure assessments) that make it applicable only to situations requiring rough screening analyses.

5.2 VARIANCE FROM THE SECONDARY CONTAINMENT REQUIREMENTS OF HAZARDOUS WASTE TANK SYSTEMS: VOLUME II: RISK-BASED VARIANCE (EPA/OSW 1987b)

5.2.1 Introduction

ICF Inc. prepared guidelines for EPA's Office of Solid Waste to estimate environmental risks posed by the release of waste constituents from hazardous waste tanks. The approach is based on the work of Barnthouse *et al*. (reviewed in Section 7.1.1 of this appendix) and EPA/OPP (reviewed in Section 4.1 of this appendix). The approach uses the quotient method in which estimated environmental concentrations (EEC) are compared to reference concentrations (RC) believed to be protective of aquatic and terrestrial species. Estimates of environmental concentrations can be obtained using computerized fate and transport models or simple mass-balance equations. The toxicity-based RCs are EPA water quality criteria, or LOELs or NOELs divided by safety factors.

The ratio of the EEC to the RC for all chemicals are summed to produce a hazard index, and the index is compared to predetermined concern levels. A hazard index less than or equal to 1.0 indicates a low probability of environmental harm. A value between 1.0 and 10 is assumed to be indicative of possible effects. A value greater than or equal to 10 indicates probable environmental harm. If the hazard index is less than 1.0, the environmental impact evaluation is considered complete. If the hazard index is greater than 10, an environmental site evaluation must be conducted.

5.2.2 Description of Method

Receptor Characterization

Both aquatic and terrestrial receptors are considered under this method. Assessments are focussed at the population level, although the value of an individual member of an endangered species is considered by using larger safety factors for toxicity values for terrestrial endangered species. The species potentially occurring at a site are identified and differentiated based on potential differential sensitivity to toxicants. Toxicity values based on indicator species which most closely resemble the sensitivity of potential receptors are selected for the risk assessment. Other characteristics of potential receptors are not considered.

Hazard Assessment

Hazard assessments are conducted at the population level, and acute and chronic toxicity thresholds are used to calculate RCs; dose-response data or community and ecosystem level responses are not considered. For aquatic toxicity, the reference concentrations are set equal to EPA's water quality criteria (WQC). If a WQC is not available for a given chemical, a chronic LOEL divided by 10, or an acute LOEL divided by 100 (whichever is lowest), is used for hazard assessment. The factors of 10 and 100 were derived from statistical and other analyses of available toxicity data and are intended to incorporate uncertainties due to test species sensitivity, acute to chronic toxicity extrapolations, and field to laboratory differences. If the WQC for a given chemical is not relevant for species or conditions at the site, site-specific criteria can be derived by recalculating a WQC or by conducting additional tests using water and/or species from the site. For terrestrial species, the lowest of the identified acute NOELs divided by 100 or the lowest of the identified chronic NOEL divided by 10 is used in the hazard evaluation.[1] An additional safety factor of 10 is used when evaluating potential impacts to endangered species. The rationale for the terrestrial safety factors was not provided.

Exposure Assessment

Specific procedures for estimating environmental exposure concentrations are not provided, although procedures ranging from simple mass balance equations to complex models are proposed. Exposures via water (for aquatic species), and via food (for terrestrial species) are the exposure pathways considered. Procedures used by EPA's Office of Pesticide Programs (EPA/OPP 1986, Section 4.1) are used to derive exposure doses from exposure concentrations in terrestrial systems. Abiotic conditions (e.g., pH, alkalinity, suspended solids, salinity) which may modify aquatic toxicity are considered during the exposure assessments. If site conditions are sufficiently different from the test conditions under which the toxicity criteria were derived, site-specific criteria may be developed.

Risk Characterization

Risks are estimated by comparing the EEC to the RC to obtain a ratio. The ratios are then summed to provide a hazard index. If the hazard index is less than or equal to 1.0, a low probability of environmental harm is assumed. A value between 1.0 and 10 is indicative of possible harmful effects. A value greater than or equal to 10 is an indication of probable harmful effects. This approach assumes strict additivity of doses (i.e., similar modes of toxicity, although chemical potency can vary). Thus, antagonistic, synergistic, or potentiating interactions are not considered.

5.2.3 Operational Resource Requirements

The level of effort required for this approach should be low to moderate for chemicals for which toxicity information already exists. Operational resource requirements will be much higher if site-specific criteria are required.

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[1] For a given species and chemical, a NOEL is identified as the highest exposure dose or concentration tested that does not produce an observable response. Identification of a NOEL requires identification of a LOEL (lowest-observed-effect-level) at a higher dose or concentration.

5.2.4 Summary

The Risk-Based Variance Procedure for evaluating ecological risks posed by the release of waste constituents from hazardous waste tanks is a semi-quantitative risk evaluation approach. The approach is similar to the quotient method proposed by Barnthouse et al. (1986; Section 7.1.1). The primary advantages of this approach are that it is relatively simple to implement and that it uses data that are readily available for many chemicals. In addition, this approach considers site characteristics, including receptor characteristics, when selecting or deriving appropriate reference concentrations. This approach has several limitations, however. Many of these limitations are inherent weaknesses of the quotient method; others are unique to this method:

- The method does not account for effects of incremental dosages (i.e., exposure-response).
- The method does not compensate for differences between laboratory and field populations.
- It cannot be used for estimating indirect effects of toxicants, such as food chain interactions.
- It has not been validated and does not quantify uncertainties.
- It does not account for other ecosystem effects (e.g., predator-prey relationships, community production/metabolism, structural shifts, etc.).
- Only one exposure pathway is considered for aquatic species and one for terrestrial species.

5.3 THE RCRA RISK-COST ANALYSIS MODEL (EPA/OSW 1984)

5.3.1 Introduction

Subtitle C of RCRA authorizes EPA to develop a national regulatory program for the management of hazardous wastes. As part of the regulatory program, EPA must provide standards for hazardous waste treatment, storage and disposal facilities. The purpose of the RCRA risk-cost analysis model, developed by ICF Inc., is to provide a consistent method to analyze the relative risks and costs of different waste management practices.

Conceptually, the model can be regarded as a three-dimensional matrix, each cell of which is a combination of a waste stream, an environment, and a waste management practice or technology. The model then calculates the risks and costs associated with each waste/environment/technology combination. Absolute risk values are not calculated in the model, only a relative scale is used. Although the model includes modules to assess risks to human health as well as risks to ecosystems, this summary only addresses the portion of the model that assesses ecological risks.

5.3.2 Description of Method

Receptor Characterization

Risks to both terrestrial and aquatic (surface water) receptors are assessed. The United States is divided into 559 areas based on three-digit zip codes. Each zip code area is defined as having one of seven possible surface water environments (large, medium, or small river, rivers with large drainage but low flow, marshes, seacoasts, and lakes). In addition, the zip code area is designated as being "more important" if it contains a National park, seashore, wilderness area, monument, river, lake shore or historic site, commercial fishing area, or public or private beach.

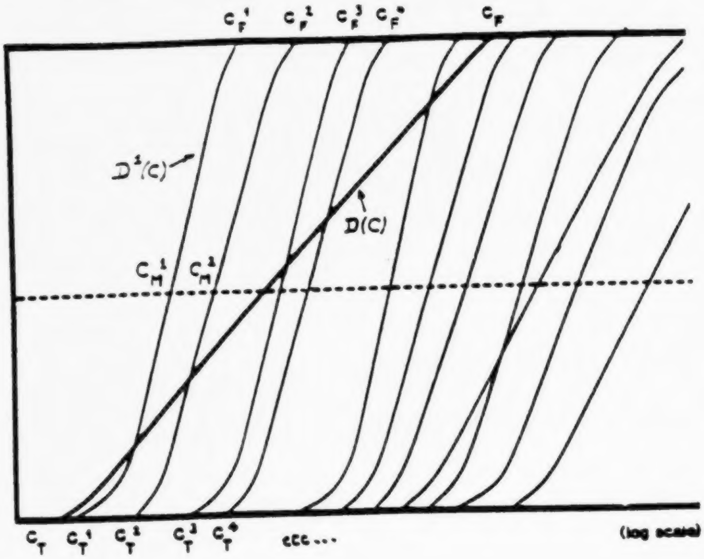
Hazard Assessment

Although the model addresses the risks associated with waste streams, the hazard assessment is conducted only for the most toxic constituent of the waste stream. Toxicity is assessed by constructing an ecosystem dose-response curve for the most toxic constituent. This curve is based on four case studies where minimal to catastrophic effects were documented. The curve derived from these case studies is shown in Figure C5-1 and is based on two assumptions (1) the ecosystem threshold is equal to the threshold concentration for the most sensitive species; (2) the range of concentrations between the threshold and catastrophic level is two to three orders of magnitude (depending on how "catastrophic" is defined, and how carefully the threshold is measured). The model's ecosystem damage function varies between 0 (no damage) when the concentration of the pollutant is at or below a threshold and 1.0 (i.e., 100% damage) at pollutant concentrations 2.5 orders

FIGURE C5-1

THE ECOSYSTEM DAMAGE FUNCTION
(Source: EPA/OSW 1984)

EXPOSURE-RESPONSE RELATIONS FOR SPECIES AND DAMAGE FUNCTION FOR ECOSYSTEM a/



C = Ambient chemical concentration in water

$D^i(C)$ = Exposure-response relation for the i^{th} species.

C_T^i = Threshold concentration for the i^{th} species.

C_M^i = Concentration giving a 50 percent response rate for the i^{th} species.

C_F^i = Concentration giving a 100 percent response rate for the i^{th} species.

$D(C)$ = Damage function for the ecosystem.

C_T = Threshold concentration for the ecosystem.

C_F = Catastrophic or fatal concentration for the ecosystem.

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a/ Assumes a given chemical.

of magnitude higher. The curve is linear with log concentrations. The lowest effect level for an individual organism is defined and used as a surrogate to estimate the extent of ecosystem level damages.

The ecosystem threshold value is derived separately for salt water and freshwater aquatic species; subcategories within these receptors are not addressed. Hazard to terrestrial systems is assessed by analogy to aquatic systems because of the lack of appropriate toxicity and exposure data for terrestrial ecosystems. For most of the chemicals, the threshold ecosystem value is chosen as the lowest of either salt water or freshwater species threshold concentrations. A different procedure is used for chemicals that bioconcentrate extensively (e.g., chlordane, hexachlorobenzene, PCB-1254, toxaphene, and mercury). For these chemicals, the dose-response curve is adjusted downward; the catastrophic damage concentration is set by analogy to the aquatic systems, but the ecosystem threshold is assumed to be 5 orders of magnitude below the catastrophic concentration on the basis of two case studies.

Uncertainty in deriving the aquatic threshold values is addressed by applying a series of safety factors to the lowest experimental threshold values. The safety factors are based on data quality, data completeness, exposure duration, and the absence of experimental threshold. The safety factors for data completeness vary from 1 to 10 and depend on the quantity and representativeness of the available data for a given chemical. If only acute data are available, empirically derived "acute-chronic ratios" for structurally similar chemicals are used. If the lowest concentration at which a chemical was tested still produced toxic effects, a threshold concentration is estimated by dividing the lowest effect concentration by 10. Default values, based on structurally similar chemicals, are used for chemicals for which no data are available.

Exposure Assessment

For the aquatic exposure assessment, surface water concentrations are estimated with distance downgradient from the point of release. A simple steady-state model is used, based on the release rate of the chemical, the flow rate of the water body, and overall decay rates. Release rates of chemicals are based on the treatment technology specified and include both continuous and intermittent releases. Exposure to terrestrial systems is assumed to be equivalent to the aquatic component of the environment, although insufficient justification is given for this approach.

Risk Characterization

A score is calculated for each cell of the waste stream/environment/treatment technology matrix. The first stage score is calculated by integrating the aquatic and terrestrial ecosystem damage functions over distance downstream from the release. The first stage score is the $\log_{10}$ of the integrated damage. The first stage scores then are modified upward by an order of magnitude if an "important environment" exists within the zip-code area. Aquatic and terrestrial scores are added to obtain the final score.

Although the score is relative, parts of the model, such as the ecosystem damage function or the exposure model, could be calibrated and validated. As knowledge of ecological effects increase, other damage functions or exposure models could easily be incorporated into this framework.

5.3.3 Operational Resource Requirements

The chemical-specific data requirements for this model are low and are readily available for many chemicals. The model development effort is complete, and the model can be run with a relatively low level of skill. As the model exists now, the ecosystem component cannot be run separately; a mainframe computer is needed to run the complete model.

5.3.4 Summary

The ecological component of the RCRA Risk-Cost Analysis Model scores the relative risk associated with different treatment technologies, waste streams, and environments. One strength of the model is that it is based on empirical studies of ecosystem responses, yet operates using readily-available data. It incorporates a measure of the areal extent of predicted damage (e.g., stream miles), and considers the presence of socially or biologically important environments. It is very flexible and could easily be modified to incorporate findings from recent or future studies. A limitation of the model is that terrestrial risk is assessed almost totally by analogy to the aquatic system. Because only the most toxic component of a waste stream is considered, it would be difficult to use the model to obtain an absolute estimate of risk. However, components of the model, such as the aquatic hazard assessment, could be combined with other exposure assessments to estimate absolute risk for individual chemicals.

6.0 METHODS/ASSESSMENTS DEVELOPED UNDER TSCA

6.1 ESTIMATING "CONCERN LEVELS" FOR CONCENTRATIONS OF CHEMICAL SUBSTANCES IN THE ENVIRONMENT (EPA/OTS 1984)

6.1.1 Introduction

The purpose of this method is to provide a framework for calculating acceptable release levels of chemicals under the Premanufacturing Notification (PMN) program of the Office of Toxic Substances. The method can be used to identify concentrations of chemicals that might cause adverse environmental effects in aquatic populations, and to identify chemicals which should be tested more rigorously under Section 5 of TSCA.

A series of assessment factors are presented to apply to the lowest observed effect level of a given chemical. Guidelines are presented to help the assessor choose the appropriate assessment factor, based on the amount and type of toxicological data available.

6.1.2 Description of Method

Receptor Characterization

The method has been developed using aquatic toxicity data and is intended to predict chronic effects at the population level. Community effects are assumed to mirror individual organism effects. The proposed approach is generic and no specific receptors are identified. Although temporal characteristics of receptors are not included, the assessment factors were developed assuming that early life stages are more sensitive than adult life stages. It also was assumed that natural conditions are less conducive to survival than laboratory conditions.

Hazard Assessment

The concern level is derived by applying an assessment factor to the lowest observed effect level for a selected chemical. The assessment factor is chosen to reflect the degree of extrapolation from the available toxicity data to data needed to assess effects in natural populations; assessment factors of 0.1, 0.01, or 0.001 are multiplied by (1) the lowest chronic effect concentration, (2) the lowest LC_{50} concentration of many acute tests, or (3) one LC_{50} from an acute test or quantitative structure-activity relationship, respectively. If there is in situ evidence of population effects from biological monitoring or full scale field studies, the assessment factor equals one. OTS's method of estimating levels of concern is intended to identify concentrations of chemicals that, if met or exceeded, might cause adverse environmental effects in populations at least 95% of the time. The possibility that adverse effects might occur below the concern level is not addressed.

The assessment factors were developed on the basis of statistical analysis of laboratory toxicity tests, considering the relationships between acute and chronic toxicity, laboratory test conditions and field conditions.

and different species sensitivities. Each assessment factor was selected to approximate a 50% confidence limit. In other words, applying the factor to a given toxicity value (e.g., one acute LC_{50} test) should encompass the toxicity value of interest (e.g., LC_{50} for the most sensitive species) 50% of the time. Toxicity of chemicals that have not been tested can be extrapolated from appropriate analogs using Quantitative Structure Activity Relationships (QSARs).

Exposure Assessment

An exposure assessment is not included as part of this method.

Risk Characterization

The methodology is designed to determine criteria for triggering concern. It is a quantitative estimation of maximum contaminant levels for individual chemicals in water that, if met or exceeded, might adversely effect aquatic organisms. The method does not consider any toxicity modifying factors or interactions with other contaminants. Statistical uncertainty is incorporated into the assessment factors. The method could be field validated.

6.1.3 Operational Resource Requirements

The method is simple and can be used with a wide variety of chemicals. The operational costs and effort are inversely proportional to amount of data available for a given chemical. If little or no input toxicity data are available, a high level of expertise on chemical property estimation methods is necessary.

6.1.4 Summary

Under this approach, an assessment factor is applied to available toxicological data to determine an environmental contaminant concentration that is likely to result in adverse effects to aquatic organisms. The strengths of the method are that it is very simple and that a hazard assessment can be performed even with very limited toxicity data. Limitations of the method include its failure to consider chemical and biological interactions, or to use exposure-response data.

6.2 ECOLOGICAL RISK ASSESSMENT IN THE OFFICE OF TOXIC SUBSTANCES, PROBLEMS AND PROGRESS (EPA/OTS 1987)

6.2.1 Introduction

The Office of Toxic Substance's Environmental Effects Branch (EEB) has developed an approach for assessing the potential ecological hazards and risks associated with new chemicals. This approach continues the work of Barnthouse et al. (1982, 1986) (reviewed in Section 7.1 of this appendix) and also previous work in OTS (reviewed in Section 6.1 of this appendix). The purpose of the ecological evaluation is to screen chemicals to identify those for which additional testing is needed based on the potential for ecological risk. The approach is a modified quotient method in which estimated environmental concentrations associated with production, use, and disposal of a chemical are compared to toxicity criteria modified by uncertainty assessment factors. Ratios which exceed one indicate a potential for ecological impact and thereby substantiate the need for further testing under the New Chemical Review Process.

6.2.2 Description of Method

Receptor Characterization

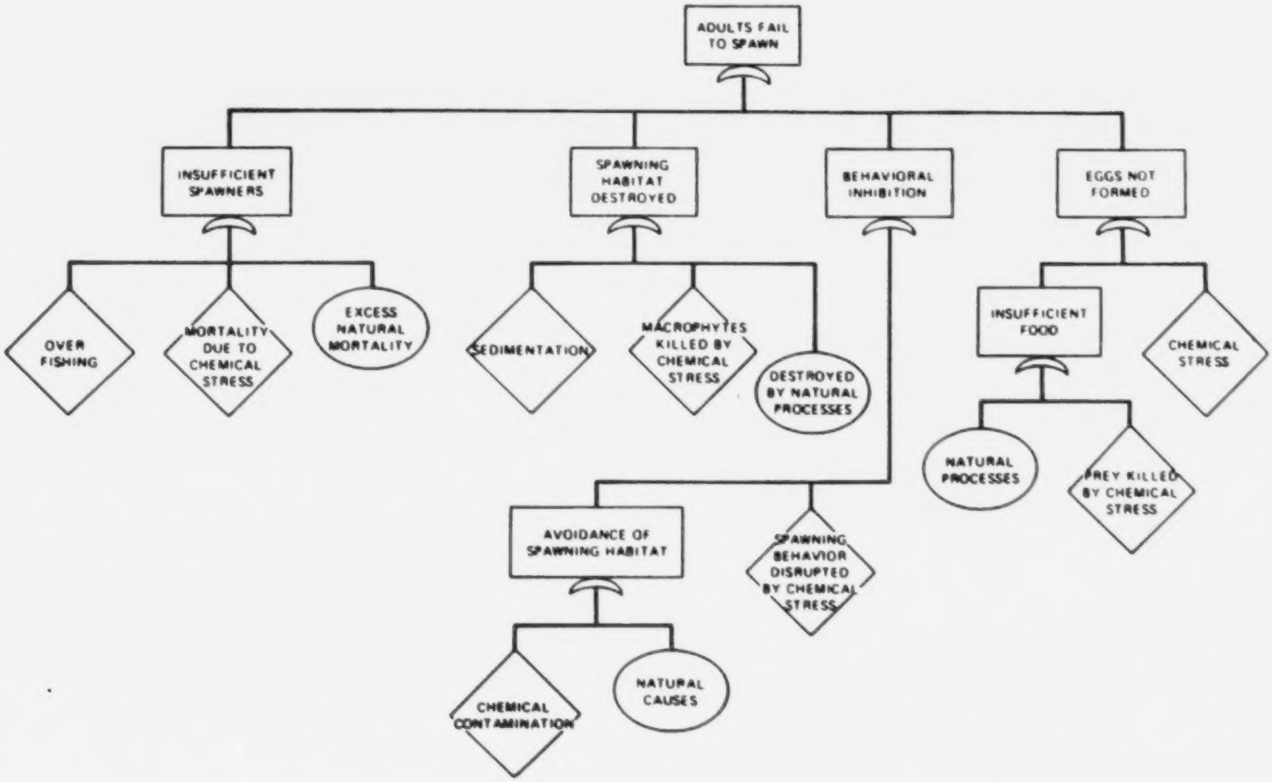
Theoretically, both aquatic and terrestrial receptors can be considered under this method, but potential impacts to aquatic systems are emphasized because the manufacture, use, and disposal of toxic chemicals most often results in discharges to aquatic environments. Assessments are focused at the population (species) level, and receptor populations are selected based on their importance as commercial, sport, recreational, aesthetic or other resources valued by society. Surrogate species are used in the quantitative evaluations of risk. Surrogate species are selected based on the general laboratory testing protocol developed by EEB and include fish, daphnids, and algae. Seasonal or life-cycle characteristics and niche characteristics of the receptors are not considered in the evaluation.

Hazard Assessment

Hazard assessments are conducted at the population level, and changes in growth, development, mortality and reproduction are identified as the endpoints of concern. Two phases of hazard assessments are conducted. The first phase is a conceptual approach in which a fault tree analysis is used to identify ecologically important impacts on populations (e.g., Figure C6-1). Potential effects on growth, development, reproduction, and mortality are classified as either direct effects or indirect effects (e.g., changes in predator prey relationships, competition, habitat). These are further divided into effects due to natural causes (e.g., climate, normal population variations) and those due to toxic chemicals. Under the latter category, acute and chronic effects are considered. Toxicity modifying factors, both biotic (e.g., competition) and abiotic (e.g., climate change) are considered. This approach provides a conceptual framework only, and therefore does not specify the type of toxicity data to be used in hazard assessment or the method by which to derive a hazard value.

FIGURE C6-1

EXAMPLE OF A FAULT TREE ANALYSIS
(Source: Barnthouse *et al*. 1986 as used in EPA/OTS 1987)


ADULTS FAIL TO SPAWN
INSUFFICIENT SPAWNERS
SPAWNING HABITAT DESTROYED
BEHAVIORAL INHIBITION
EGGS NOT FORMED
OVER FISHING
MORTALITY DUE TO CHEMICAL STRESS
EXCESS NATURAL MORTALITY
SEDIMENTATION
MACROPHYTES KILLED BY CHEMICAL STRESS
DESTROYED BY NATURAL PROCESSES
INSUFFICIENT FOOD
CHEMICAL STRESS
NATURAL PROCESSES
PREY KILLED BY CHEMICAL STRESS
AVOIDANCE OF SPAWNING HABITAT
SPAWNING BEHAVIOR DISRUPTED BY CHEMICAL STRESS
CHEMICAL CONTAMINATION
NATURAL CAUSES

The second phase of the hazard assessment involves the derivation of a "concern level", which is a chemical concentration that if equaled or exceeded would justify further testing of a chemical. Toxicological endpoints are defined by the results of acute, chronic, or subchronic tests and are reported as LC_{50}s, EC_{50}s, and MATCS. Toxicity values for the most sensitive species are used to determine concern levels. Concern levels are derived by dividing the toxicity value (LC_{50}, EC_{50}, or MATC) for a new chemical or an analog by an "assessment factor." Assessment factors range from 1 to 1000 by multiples of 10, and are based on the degree of uncertainty associated with the toxicity values (reviewed in Section 6.1 of this appendix). An assessment factor of 1 is used when the toxicity value is based on the results of a field test, and an assessment factor of 1000 is used when there are only two or three laboratory tests available for the new chemical or an analog, or if a toxicological value is derived from a Quantitative Structure Activity Relationship.

Exposure Assessment

Specific procedures for exposure assessment are not specified in the method, but contaminant concentrations in water resulting from the production, use, or disposal of a particular TSCA chemical must be estimated or measured.

Risk Characterization

Environmental concentrations that result or could result from simulated or actual conditions of chemical production, use, and disposal are compared to the "concern level." Ratios that exceed 1 indicate the potential for ecological impact and justify the need for further testing.

Using this approach, the potential for adverse effects on aquatic organisms following exposures to a single chemical via a single route of exposure are evaluated; multiple chemicals and multiple pathways are not considered. The method is broadly applicable as a screening methodology to identify areas for further study. The method, as currently applied, does not address uncertainty in the exposure or risk estimate. Uncertainty in the hazard assessment is addressed via the use of assessment factors. The method has not been validated, field-tested, or calibrated.

6.2.3 Operational Resource Requirements

The resource requirements of the EEB risk assessment method are low. The approach is relatively simple to implement and requires minimal data, most of which is usually readily available for the chemical being evaluated or an analog.

6.2.4 Summary

The method currently used by EEB for identifying chemicals for further study is a modified quotient method. The primary advantages of this approach are that it is easy to implement and has minimal data requirements. Consequently, it is an approach useful for the rapid screening of new chemicals. There are, however, several limitations associated with this approach, and most of these limitations are inherent limitations of the quotient method: it does not routinely take into account exposure-response; it does not consider indirect effects; it has no predictive capabilities; and it addresses the uncertainty associated with variation in taxonomic and life-stage sensitivities with generic application factors rather than factors derived specifically for a chemical group or for species in specific regions.

EEB has recognized these deficiencies and has suggested additional approaches for consideration in ecological assessments. The goal of EEB is to be able to assess both direct and indirect effects, and eventually to evaluate potential for recovery. The Ecosystem Uncertainty Analysis (EUA) of Barnthouse et al. (1982, 1986; see Section 7.1) is regarded by EEB as a potential tool for evaluating the potential impacts of indirect toxic effects (e.g., on other trophic levels) as well as direct toxic actions on populations. The model used to illustrate the EUA methodology, SWACOM, attempts to predict the effects of a toxicant on a pond ecosystem. Included in the assessment are estimates of direct mortality and indirect changes in population, community, and ecosystem structure. The Risk Analysis and Management Alternatives (RAMAS) approach is regarded as a potentially viable method of addressing the effects of a toxicant on the age/size class of any population. RAMAS estimates direct toxic action on the life stages of various populations by the use of a Monte Carlo simulation of age structured populations. It is designed to address the probability that a population will fall below a given threshold within a specified time, and also predicts the number of individuals within a given age class. EEB is currently evaluating the potential utility of these and other methods.

7.0 OTHER METHODS/ASSESSMENTS

7.1 USERS MANUAL FOR ECOLOGICAL RISK ASSESSMENT (Barnthouse et al. 1982, 1986)

7.1.1 THE QUOTIENT METHOD

7.1.1.1 Introduction

The quotient method (QM) (Barnthouse et al. 1986) compares an estimated environmental concentration (EEC) to a toxicological benchmark (e.g., LC50, GMATC, EPA AWQC). The purpose is either to (1) predict if an EEC is of concern, or (2) rank a series of contaminants or contaminant sources by their potential for producing adverse environmental effects. The procedures were developed to support EPA's synfuels research program.

7.1.1.2 Description of Method

Receptor Characterization

The type of receptor selected under this approach depends on the type of benchmark value used. The same type of toxicological benchmark (e.g., MATC or LC50) is required for all chemicals to make comparisons between quotients. Moreover, a single representative benchmark value is required for each chemical. This value could be the toxicological benchmark value for either an indicator or sensitive species. Alternatively, a composite benchmark such as an Ambient Water Quality Criterion, designed to be protective of the majority of aquatic species, could be utilized.

In general, toxicological benchmarks (TBs) for aquatic indicator species (population level) are used, but TBs for terrestrial species are available for some types of exposure routes. The approach is usually generic, but a small degree of specificity can be introduced by the selection of appropriate indicator species. If exposures are expected to be brief, on the order of days, either adult or sensitive life-stage benchmarks could be used as the season dictates. For chronic exposures, LC1s or MATC benchmarks are most appropriate.

Hazard Assessment

There are two statistical types of toxicological benchmarks: (1) those that prescribe an effect level (e.g. LC50 or LC1) based on a dose-response relationship, and (2) those that are based on hypothesis testing. The second type of benchmark is exemplified by the MATC which is assumed to lie between a no-observed-effect level (NOEL) and a lowest-observed-effect level (LOEL). To identify NOELs and LOELs, responses at exposure concentrations are compared with control responses (no exposure) to test the null hypothesis that they are the same as the control responses. Using conventional hypothesis testing procedures that set alpha = 0.05 and leave beta unconstrained, one avoids declaring that a concentration is toxic when it is not with a high degree of certainty (type I error). However, there is an undefined chance of declaring that a concentration is not toxic when it is (type II error). Thus, toxicological benchmarks based on dose-response relationships are preferable to those obtained by hypothesis testing.

If the quotient method is used primarily as a screening tool to rank chemicals according to their potential for adverse environmental effects, the quotients are compared directly. If the QM is used to provide an estimate of environmental risk, uncertainty about the relationship of the TB to the organisms and exposure situation at hand is treated by the application of safety factors. Recently, application of a string of safety factors, each representing a different source of uncertainty, has become common. The underlying belief appears to be that "everything will go wrong at once", and the result can be an extremely conservative evaluation.

Exposure Assessment

This method does not include an exposure assessment.

Risk Characterization

"Risk" is based on the ratio of the EEC to the appropriate toxicological criterion. For single chemical assessments, concern levels have been set arbitrarily as follows: no concern, quotient ≤ 0.1; possible concern, $0.1 <$ quotient ≤ 10; probable concern, quotient > 10. For multiple contaminant screening, the quotients are ranked relative to one another.

7.1.1.3 Operational Resource Requirements

Computationally, the quotient method is extremely simple. However, the data requirements can be extensive depending on the benchmarks and chemicals under consideration.

7.1.1.4 Summary

The quotient method (QM) can help identify EECs that are unlikely to be of concern. When the EEC exceeds the lowest toxicological benchmark concentration, the QM cannot predict the degree or type of potential environmental impacts. The method does not lend itself to consideration of multiple routes of exposure, food chains, or any estimates of uncertainty.

The QM is useful mostly as an initial screening tool. With appropriate professional judgment, the QM could provide a useful method of identifying contaminants that are below levels of possible concern. If a few contaminants must be selected to represent the waste stream of a particular source category in more extensive ecological risk modeling, the QM can provide a useful first tier screen. Even this limited application, however, can produce misleading results if the quality of information available for the contaminants is variable, or if the slope of the dose-response curve differs drastically between chemicals.

7.1.2 ANALYSIS OF EXTRAPOLATION ERROR

7.1.2.1 Introduction

The analysis of extrapolation error (AEE) is a method for estimating the probability that an environmental contaminant concentration (EEC) exceeds measured or unmeasured toxicological benchmark values (TBVs). Unmeasured TBVs are extrapolated from available information. The uncertainty associated with the extrapolation is quantified through regression analysis rather than by the application of safety factors. The AEE method emphasizes that uncertainty in estimations contributes to risk.

7.1.2.2 Description of Method

Receptor Characterization

The AEE provides a methodology for estimating unmeasured toxicological benchmarks. As a consequence, receptor characterization is far more flexible than with the previously discussed quotient method. The most extensive toxicological data available to support statistical regression analyses are for aquatic species. For short-term exposure scenarios, toxicological endpoints for adults or sensitive life stages can be chosen according to the seasonality of the anticipated exposure. For chronic exposures, maximum allowable toxicant concentrations (MATCs) or LC1s are more appropriate.

Hazard Assessment

In the absence of appropriate laboratory test data for a species and toxicological benchmark of interest, the benchmarks are extrapolated from available toxicity data using regression analysis. The AEE hazard assessment consists of four steps: (1) definition of the endpoint for the risk assessment in terms of a toxicological endpoint (e.g., the probability of exceeding the brook trout MATC); (2) identification of the existing datum most closely related to the endpoint (e.g. a rainbow trout 96 hr LC50); (3) identification of the necessary extrapolations (e.g. rainbow trout to brook trout, 96 hr LC50 to MATC); and (4) the statistical regression analysis.

In step four, an errors-in-variables regression model provides the best estimate of the unmeasured assessment endpoint from the available data. The variance of a single predicted Y-value for a given X-value is the appropriate value to use in calculating confidence intervals. The interest is in the uncertainty concerning an individual future observation of Y, such as toxic threshold, for an untested species-chemical combination. If more than one extrapolation is required, the Y-value from the first extrapolation becomes the X-variable in the second extrapolation.

The variance is equal to the sum of the variances from the individual extrapolations. The variance associated with the extrapolation would depend in part on variation in the real world, e.g., inter-species differences. The variance would also reflect the number of measured data points available for the extrapolation. Thus, the variance associated with the extrapolation would be higher with less well-characterized relationships.

Barnthouse and associates validated the double extrapolation method for estimating an MATC of one aquatic species from the acute LC50 of another where laboratory data permitted. They found that the predictions based on the AEE method were more accurate than the application of generic safety factors. The major advantage of the AEE is that the uncertainty of each estimate is quantified.

Exposure Assessment

Use of the AEE method presupposes that an exposure assessment has already been performed.

Risk Characterization

The AEE method defines ecological risk as the probability that the ECC exceeds the toxicity benchmark value (TBV). Assuming that the ECC and TBV are independent and log-normally distributed, then: Risk = Prob(log(TBV) - log(ECC) < 0). Figure C7-1 illustrates this risk as the shaded area of overlap of the ECC and MATC probability distributions. Thus, the AEE method can incorporate both the uncertainty in the value of the toxicological endpoint and the uncertainty in the estimate of environmental concentrations.

7.1.2.3 Operational Resource Requirements

The AEE method makes maximal use of available toxicological data to estimate unmeasured toxicological benchmarks and/or to estimate the uncertainty associated with either measured or unmeasured TBVs. If a user is interested in a particular extrapolation for which a regression analysis has already been performed with a reasonably up-to-date toxicological data base, little computational effort is required to complete an AEE assessment. If a user intends to make a novel extrapolation, an extensive literature search and review is required, followed by a moderate computational effort.

7.1.2.4 Summary

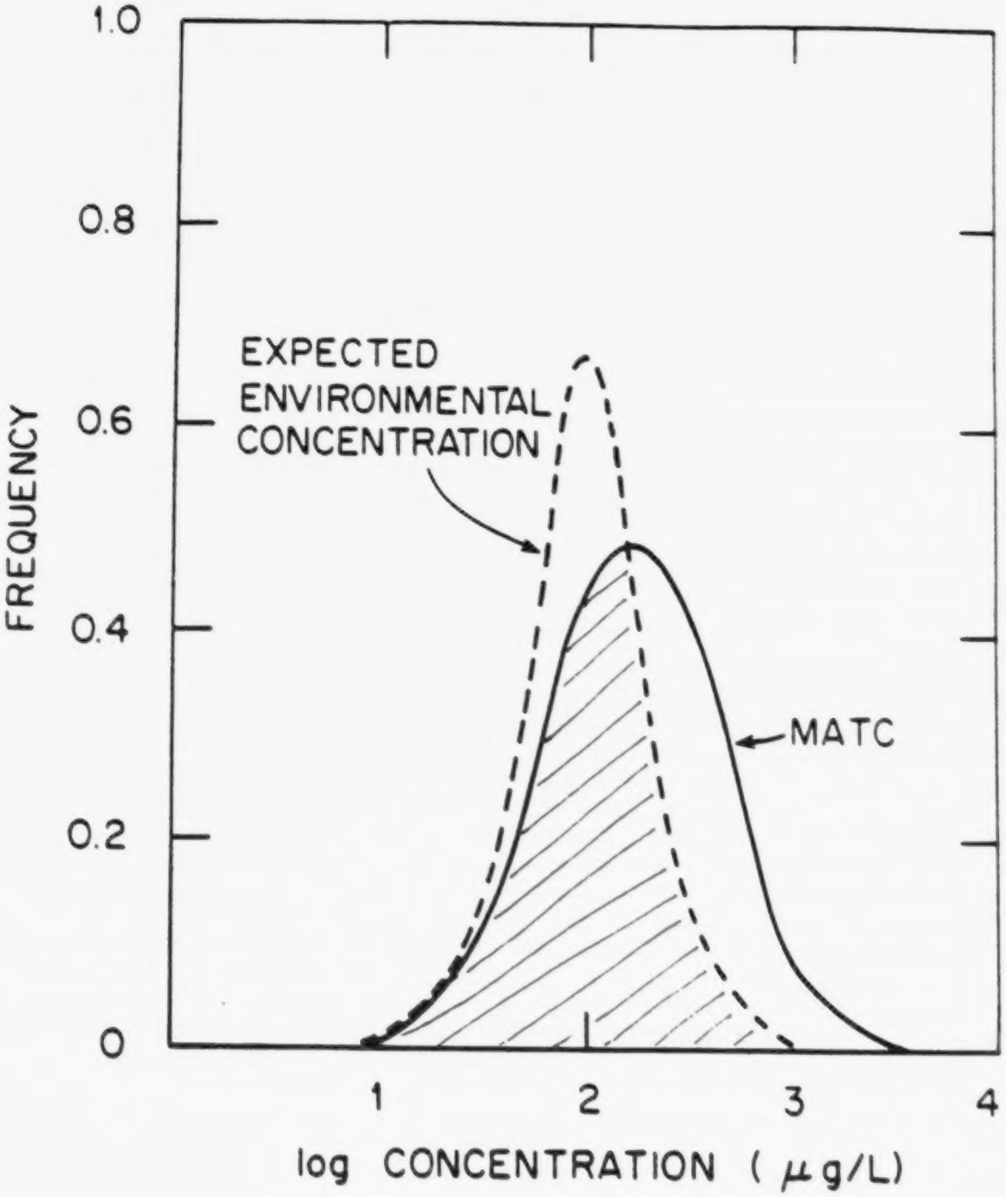
The AEE, like the quotient method, is best suited for answering the question "is there a high probability of concern or not". It does not estimate the magnitude of ecological effects expected in situations in which the EEC exceeds the toxicological benchmark.

This technique could also be used for ranking the potential ecological risk posed by a series of chemicals. The estimates of uncertainty associated with each TB would help identify which ratios of EEC/TB are significantly lower or higher than others.

Compared with the quotient method, the AEE has the advantage of defining and quantifying the terms of an extrapolation using a large amount of toxicological data. Measurement of the variability in species' sensitivity to toxicants and in the relationship of various toxicological benchmarks to each other provides an estimate of the uncertainty associated with unmeasured

FIGURE C7-1

OVERLAP IN EEC AND MATC PROBABILITY DISTRIBUTIONS
(Source: Barnthouse *et al*. 1986)



toxicological benchmarks. The explicit estimation of uncertainty should assign higher probabilities of adverse effects for chemicals which are less well-characterized.

7.1.3 EXTRAPOLATION OF POPULATION RESPONSES

7.1.3.1 Introduction

The purpose of the extrapolation of population responses (EPR) method is to extrapolate from individual-level responses in laboratory settings to population-level responses in the field. The EPR method first develops life-stage-specific exposure-response functions for a single species. These form the basis for estimating changes in a population's reproductive potential with toxicant concentration as well as the confidence limits of the relationship.

7.1.3.2 Description of Method

Receptor Characterization

Application of the EPR method requires a life-stage characterization of a receptor population. Barnthouse et al. (1986) developed an example for a fish population in which all life stages are exposed through the same medium. The number of life stages is variable, depending on the organism and the quality of data available for each stage. A life table including the following information is required for each age after the first breeding year: the proportion of mature females, the fecundity per mature female, and the cumulative probability of survival from the age of reproductive maturity to each future age.

Hazard Assessment

The life-stage-specific concentration- or exposure-response functions form the backbone of the EPR method. Exposure-response data sets can be fitted to a logistic equation using nonlinear least squares regression. The confidence limits (uncertainty band around the fitted regression) can be estimated from the elements of the variance-covariance matrix. Because full life-cycle exposure-response data are rarely available, extrapolation from the few well studied species will often be necessary.

Barnthouse et al. (1986) used the analysis of extrapolation error (AEE) method to estimate the chronic LC_{25} and one of the exponential parameters for exposure-response functions for 60 species/contaminant/experimental condition combinations. The extrapolated response functions and the uncertainty bands were verified for the 60 data sets with favorable results.

Exposure Assessment

This method presupposes an exposure assessment.

Risk Characterization

The endpoint considered for the risk assessment in the Barnthouse et al. (1986) example was the reproductive potential of a female recruit into a fish population. Lifetime reproductive potential is dependent on the probability of survival to successive life stages and age-specific fecundity. From the exposure-response curves developed for each life stage, the probability of survival from one age to the next is estimated. Finally, the exposure-response function for reproductive potential is constructed using a log-probit model. The appropriate confidence limits are used to define a band of uncertainty around the exposure-response function as illustrated in Figure C7-2. Barnthouse et al. (1986) found narrow confidence limits associated with between species extrapolations and large confidence limits in situations where chronic benchmarks were extrapolated from acute values.

The final step is estimating the probability of various effect levels given an environmental concentration. Barnthouse et al. (1986) did not elaborate on this point. From Figure C7-2, it is clear that the most simple approach would be to define concentration levels of no concern, intermediate concern, or serious concern. Alternatively, one could define the probability of exceeding a certain percentage reduction of female reproductive potential.

7.1.3.3 Operational Resource Requirements

If full life-cycle exposure-response data are not available for a species of interest, the function could be extrapolated from information on other species. The degree of effort would be entirely dependent on the number of extrapolations required. Barnthouse et al. (1986) have compiled and presented a large body of freshwater fish acute and chronic toxicity test information. A computer software statistical package is required for fitting experimental data to log-probit regressions. The remaining computations require a moderate amount of computer assistance.

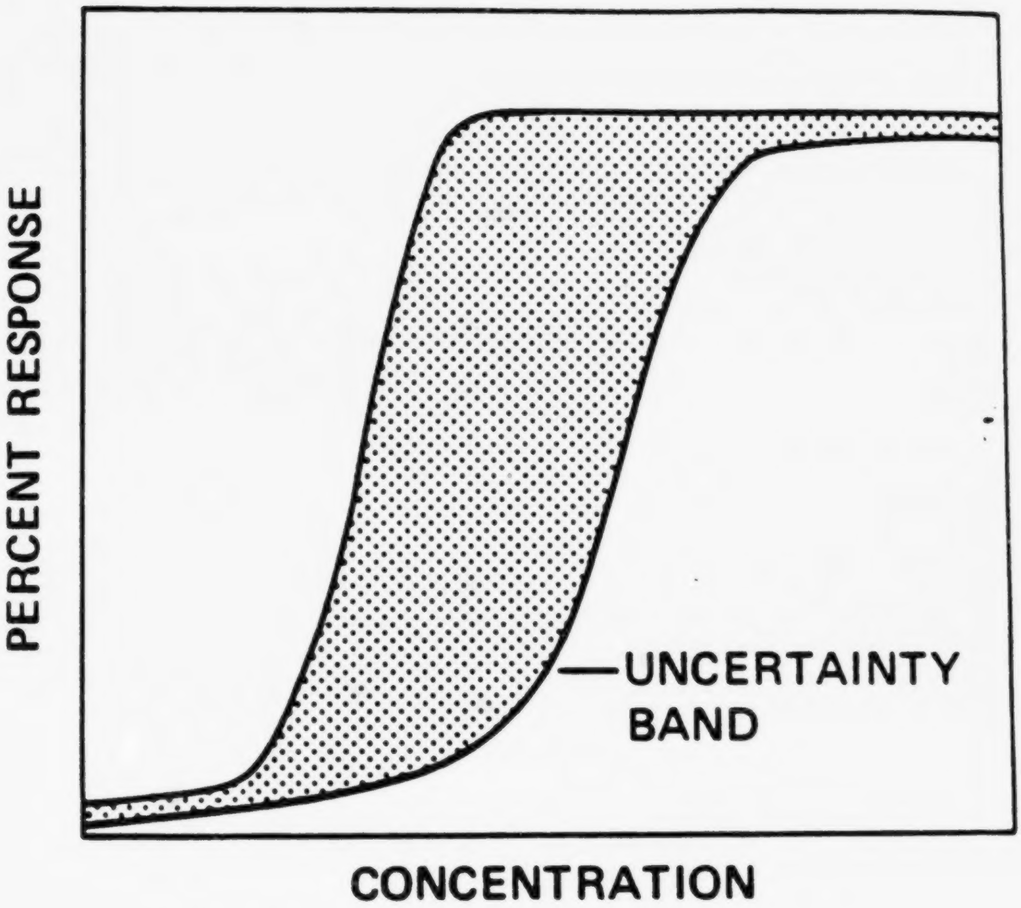
7.1.3.4 Summary

The extrapolation of population responses (EPR) method is very similar to simple analysis of extrapolation error with two possible improvements. The EPR method combines information from several life stages into a single effect level, thus offering the potential for a more accurate representation. Second, a variety of effect levels can be considered as endpoints.

The EPR methodology provides several advantages over the use of MATCs for setting regulatory standards for water criteria. Barnthouse et al. have pointed out that the use of hypothesis testing to estimate MATCs leads to nonconservative risk assessments. The probability of committing type II error (i.e., accepting a concentration level as non-toxic when it is in fact toxic) is unconstrained. The less rigorously the experiment is conducted (smaller sample sizes or poor control of other environmental factors), the higher a concentration will have to be to produce response levels that are significantly different from control levels. With the EPR method, Barnthouse et al. estimated LC_{10}s for several species that were an order of magnitude

FIGURE C7-2

PERCENT RESPONSE VS. CONCENTRATION
(Source: Barnthouse _et al_. 1986)



lower than the estimated MATCs. For example, the brook trout MATC for methylmercury (0.53 ug/liter) corresponds to a 60 to 78 percent reduction in reproductive potential in brook trout according to the EPR method.

A limitation of this type of model, however, is that a large amount of the toxicant-induced mortality that affects female reproductive potential occurs in the young, pre-reproductive age-classes. If recruitment into the breeding population in free-living populations is in part density-dependent, a given percentage death in a pre-reproductive cohort might have a much smaller percentage effect on recruitment into the breeding population.

7.1.4 ECOSYSTEM UNCERTAINTY ANALYSIS

7.1.4.1 Introduction

The ecosystem uncertainty analysis (EUA) method attempts to extrapolate from single species toxicity effects to ecosystem level effects. In particular, the model attempts to address higher order effects for concentrations that are well below acute LC_{50} values. The EUA emphasizes the uncertainty associated with each level of extrapolation. In principle, any sort of model of biotic community relationships could be used. The key feature of the uncertainty analysis is the use of simulation techniques and probability distributions for underlying parameters to generate probability distributions for effects.

7.1.4.2 Description of Method

Receptor Characterization

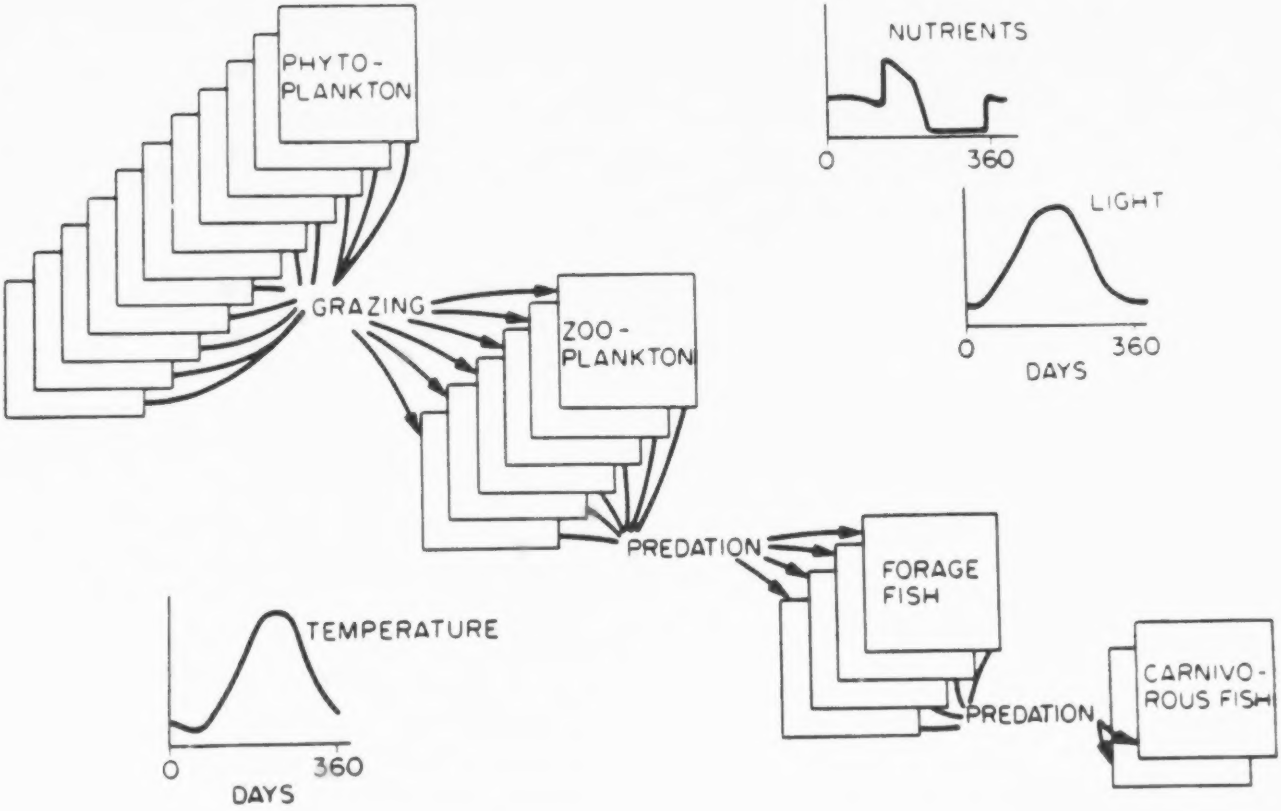
Receptor characterization depends upon the actual "ecosystem" model used. As an example, Barnthouse et al. (1986) used the Standard Water Column Model (SWACOM). SWACOM is a computer model designed to simulate the pelagic portions of a north temperate lake ecosystem. The model, illustrated in Figure C7-3, includes ten phytoplankton populations, five zooplankton populations, three planktivorous fish populations, and a top carnivore population. The populations within each trophic level may have differing sensitivities to toxicants. Seasonal variation in abiotic factors constrain the seasonal behavior of the populations and their relationships.

Hazard Assessment

SWACOM model parameters include processes such as grazing, respiration, and susceptibility to predation. The expected change in each parameter value in response to exposure to a given toxicant concentration is expressed by an element of an effects matrix. For each of the effects in the matrix, an estimation of uncertainty is required. The uncertainty can either be measured from appropriate data or estimated based on professional judgment. Usually, however, the appropriate data are not available for the parameters used by SWACOM.

FIGURE C7-3

THE SWACOM COMPUTER MODEL
(Source: Barnthouse et al. 1986)


PHYTO-
PLANKTON
NUTRIENTS
0
360
LIGHT
0
360
DAYS
GRAZING
ZOO-
PLANKTON
PREDATION
FORAGE
FISH
TEMPERATURE
0
360
DAYS
PREDATION
CARNIVO-
ROUS FISH

To circumvent the lack of data relating toxicant concentrations to the parameters used by the SWACOM model, Barnthouse and associates suggested using a "general stress syndrome" to depict each population's response to sublethal toxicant concentrations. For example, a general stress response by grazing fish might include decreased respiration, lower temperature optima, and increased mortality and susceptibility to predation. To extrapolate from acute toxicity LC_{50} values to effects on respiration, susceptibility to predation, etc., Barnthouse et al. (1986) assumed that (1) organisms respond to all toxicants in a uniform manner, and (2) all parameters (e.g., respiration, susceptibility to predation) are changed by the same percentage in response to a toxicant exposure.

This extrapolation is extremely tenuous and does not lend itself to an analysis of uncertainty. It is necessary to know not only the percentage change in parameters, but also the uncertainty to be associated with the change. Barnthouse et al. (1986) assumed that "all parameter changes have an associated uncertainty of plus or minus 100%."

Exposure Assessment

This aspect of modeling was not addressed.

Risk Characterization

The endpoints of EUA analysis are operationally defined in terms of "effects variables". These must be predetermined and might include effects such as a 25% decrease in game fish biomass or a 50% increase in algal biomass.

SWACOM simulates the population dynamics of the phytoplankton, zooplankton, grazing fish, and one top carnivore. Competition among species within a trophic level, and predation or grazing by higher trophic levels on lower trophic levels, are modeled. In addition, an annual cycle of nutrient flux, light, and temperature affect growth and reproduction. Environmental concentrations are compared to the effects matrix for each species and each parameter to determine the direction and magnitude of the effect.

The ecosystem is then modeled using a Monte Carlo simulation. At the start of each run, parameter values are drawn from their statistical distributions. In this way, uncertainties are propagated through the model ecosystem. The simulation continues until a stable frequency distribution of results is obtained. In this way, the uncertainties of extrapolating laboratory data to the field should become statements about the uncertainty of an undesirable effect. Thus, the risk of a specified adverse effect level is a function of both of direct toxicity and the effect of uncertainty resulting from the extrapolation.

The ecosystem effects calculated by EUA could not be predicted without this form of analysis. For example, increasing bluegreen algal blooms with increasing toxicant concentration appears counterintuitive. The SWACOM adaptation, however, indicated that even though a compound may be toxic to the algae, reduction in sensitive grazing organisms can more than compensate for the adverse direct effects on phytoplankton.

7.1.4.3 Operational Resource Requirements

In general, the data requirements for ecological uncertainty analysis are large. First, a reasonably large number of receptor populations are required to simulate a microcosm. Second, exposure-response data, mechanisms of action, and sublethal toxicant effects are required for reasonably realistic modeling efforts using a model such as SWACOM. Finally, a large number of input parameter distributions must be obtained or estimated.

To preserve the influence of the uncertainty in the input parameter distributions, Monte Carlo simulation techniques are most appropriate. The number of iterations of the model required to generate a reasonably stable output distribution can in theory be quite high.

7.1.4.4 Summary

The compromises that are needed to implement a model like SWACOM reflect a fundamental shortcoming in available data. Some of the more realistic options for modeling the effects of toxicants at population and community levels require far more information on sublethal effects than simple acute toxicity or even chronic toxicity testing typically provide. To the extent that models like SWACOM are scientifically verified (e.g., scientifically reasonable), the need for qualitatively different toxicological data is apparent. The alternative solution is to use models that use mortality as an endpoint, as does the CERCLA Type A Assessment Model (DOI 1987a).

7.2 REGIONAL ECOLOGICAL ASSESSMENTS: CONCEPTS, PROCEDURE AND APPLICATIONS (Ballou et al. 1981)

Argonne National Laboratory (ANL) developed several approaches for conducting regional assessments of the potential ecological impact of energy-development activities. Some of the primary approaches proposed include (1) a regional ecological characterization scheme, (2) procedures for estimating crops and natural vegetation at risk from gaseous pollutants, (3) procedures for estimating crop yield reductions, (4) procedures for estimating and quantifying direct land disturbance, (5) a data base and mapping procedure for predicting overlap with endangered or threatened species habitat, and (6) the use of ecosystem resiliency and diversity as a tool for ecological assessment. The scope of the project focused primarily on energy impacts in the Midwestern United States.

Below, each of these approaches is discussed in the context of its usefulness for ecological risk assessments.

7.2.1 REGIONAL ECOLOGICAL ASSESSMENT UNITS

7.2.1.1 Introduction

ANL developed an ecological receptor characterization scheme based on regional physiographic units. This classification scheme reflects regional homogeneity of environmental variables, and thus is based on ecologically meaningful characteristics. Such a classification scheme facilitates generalizations regarding the impacts of energy-related or other activities on regionally-homogeneous ecological areas.

7.2.1.2 Description of Method

Receptor Characterization

ANL categorized the terrestrial environment into approximately 90 "ecological assessment units (EAUs)" defined by commonalities of bedrock/substrate, landform, soils, natural vegetation, and land use (e.g. Piedmont lowland, unglaciated Allegheny plateau). The EAUs were built from an existing national classification system based on climate, soils, and topography. EAUs were derived from physiographic units that were statistically homogeneous according to land use and cover type. Within each of the EAUs, ANL developed a county-specific data base that included the generalized land-use characteristics (e.g. pasture, cropland) and potential natural vegetation (e.g. maple-basswood forest, oak savannah), and the percent cover for each county by these categories.

7.2.1.3 Operational Resource Requirements

This approach for receptor characterization is based on readily available information. The initial data gathering and compilation would be resource-intensive. However, because the initial collection and compilation has been completed by ANL, application of this approach should be inexpensive and require minimal individual expertise and effort.

7.2.1.4 Summary

The major advantage of the EAU approach for receptor characterization is that large-scale energy activities or other large-scale ecological stresses can be related to broad, ecologically similar regions. For example, the Adirondack Mountains, Allegheny Mountains, and Superior Uplands are each physiographic units that are highly sensitive to acid rain deposition because they are characterized by bedrock and soils with low buffering capacities due to a lack of base minerals. Based on similar interpretations of common characteristics among EAUs, potential impacts to related ecosystems can be estimated. This approach is for receptor characterization only, and must be combined with hazard and exposure information for use in ecological risk assessments.

7.2.2 DETERMINATION OF CROPS AT RISK AND ESTIMATING CROP YIELD REDUCTIONS

7.2.2.1 Introduction

One of the major potential impacts of fossil-fuel burning plants is reduced crop yield and damage to both agricultural and natural vegetation from elevated sulfur dioxide (SO_2) levels. ANL used reported exposure-response data derived from energy technology assessments to identify species of crops and natural vegetation types at risk from future releases of SO2. Also, exposure-response data were combined with model-based estimates of exposure to determine crop yield reductions from estimated releases. Yield reductions were determined for both acute and chronic exposure scenarios. The risk of significant crop yield reduction (i.e., > 5%) was determined by the number of concentration threshold exceedances.

7.2.2.2 Description of Method

Receptor Characterization

ANL identified the dominant crop species and natural vegetation species within each county of the U.S. Crop data by county was obtained from the 1974 Census of Agriculture. Information on natural vegetation communities was derived using Kuchler's (1974) classification of vegetative communities in the U.S. (Am. Geo. Soc. Sp. Pub. No. 36). Dominant vegetative species were assumed to be representative of other vegetation within the community. Only terrestrial species were considered in the classification. The most susceptible stage of growth for each species was identified.

Hazard Assessment

The hazard assessment consists of two phases: a screening phase in which available toxicological data are used to determine the relative sensitivities of the various dominant vegetation types to SO_2, and a more detailed assessment phase in which available toxicological data are used in a quantitative determination of crop-specific effect levels. The screening phase is limited to determination of impacts following acute, high-level exposures. The more detailed assessment phase evaluates impacts following both acute and chronic exposures. Presumably, the most sensitive endpoint was used in determining relative species sensitivities. Although species-specific data are used, the results of the assessment are assumed to be representative of potential community impacts. There is no treatment of uncertainty in the hazard assessment.

In the screening phase, ANL classified 93 of their 116 vegetation categories according the sensitivity of the dominant plants to SO_2. Plants were classified qualitatively as sensitive, intermediate, and resistent. The classification was based on an extensive literature review of the exposure-response of a variety of plants to SO_2. Average 3-hour maximum SO_2 concentrations were used to predict impacts on vegetation.

In the detailed phase, ANL used estimates of short-term peak concentrations to determine impacts on crop yield following acute exposures. Impacts following chronic low-level exposure were determined using studies on yield reduction in soybeans. Based on the available literature, a damage threshold of 234 ug/m^3 was determined for soybeans. Although a hazard assessment for chronic exposures was conducted for soybeans only, the approach of threshold identification can be used for any species for which adequate exposure-response data are available.

Exposure Assessment

Exposure concentrations were determined for both short-term and long-term releases. Spatial and temporal variations in exposure concentrations were considered using short-term and long-term dispersion models. Only exposure via air was considered.

Acute exposures to SO_2. ANL developed modeling techniques to estimate the peak ground-level concentrations of air pollutants near a point source as a function of power plant capacity and emission rate. The techniques used short-term mathematical models to provide estimates of peak ground-level concentrations and the distances from the source at which they occur. In this screening methodology, the critical meteorological conditions under which peak concentrations may occur are identified and the corresponding concentrations determined. Thus, the worst case scenarios are modeled and the ground surface area exposed to various peak SO_2 levels is defined.

Chronic-Damage Air Quality Modeling. A slightly different air quality modeling approach was used to estimate doses following long-term, low-level pollutant exposure. Under this approach, the total number of multiple-hour exposure periods in which a given threshold concentration is exceeded is determined. For the purposes of their assessment of soybean yield loss, ANL chose a threshold value of 234 ug/m^3 for a 4-hour exposure period based on empirical data. A Gaussian dispersion model was used to determine exposure concentrations. Total dose was determined by summing the total accumulated dose for each 4-hour period in which the threshold value was exceeded. Spatial contours of the total SO_2 dose were developed.

Risk Characterization

The contours of the total SO_2 dose determined in the exposure assessment are used to estimate the risk of significant crop yield reduction by comparing estimated concentrations with available crop dose-response information.

Under this quantitative approach, only potential damage to a single crop species following exposures to a single compound via a single route of exposure are evaluated. There is no treatment of uncertainty. The approach has been partially validated by comparing modeling results with empirical data, and the results were in good agreement. The approach is flexible, so that if sufficient dose-response information is available, it can be applied to similar situations to determine potential damage from airborne pollutants to other plant species.

7.2.2.3 Operational Resource Requirements

This approach is expensive and labor-intensive. Large amounts of data must be compiled to determine dominant species within counties or other designated regions, and to determine dose-response relationships for each species and each chemical evaluated. Additional expertise and costs are associated with the air modeling effort. The costs and level of skill associated with interpretation of the available data are moderate.

7.2.2.4 Summary

The procedure for crop loss assessment proposed by ANL is a quantitative worst-case approach to estimating the areal extent of significant crop yield reduction (i.e., in excess of 5 percent) from emissions of phytotoxic gases. The primary advantages of this approach are that it is flexible and can be applied to estimate damage to other plant species from various air pollutants. However, the approach is cost- and data-intensive, and its applicability is limited somewhat by a current lack of dose-response data for many species and pollutants. In addition, only damage to plants is estimated and is assumed to be representative of damage to the community or ecosystem.

7.2.3 DETERMINATION OF LAND USE DISTURBANCES

7.2.3.1 Introduction

ANL developed algorithms for quantifying the amount of land disturbed by energy activities. The proposed methodology determines the amount of land required for power plant sites or for mining, the amount of additional land disturbed by these activities, and the significance of the impacts. Under this approach, the amount of forest, grassland, or other natural habitat disturbed is of greatest concern for ecological assessments. Impacts from a number of processes are considered, including building, moving soil, noise, human presence, road construction, and traffic.

The endpoint of concern in this assessment is loss of land use. The stresses in this assessment are direct and indirect physical stresses (e.g., land destruction (direct), human presence and noise (indirect)) rather than chemical, and therefore hazard assessments as typically conceived are not appropriate. Exposure assessment determines the amount of overlap of the physical disturbances with the land. "Risk" in the context of this approach is not a determination of the probability of an effect level, but rather an estimate of damage (land usage loss).

Below, we discuss the aspects of this approach that are applicable to risk assessment.

7.2.3.2 Description of Method

Receptor Characterization

The receptor under this approach is land, and land is differentiated by land use. Land use categories include crop land, pasture, range, forest, urban land, Federally-owned land, and other rural land (e.g., roads, farm buildings, swamps, and barren land). It was assumed that Federal land is covered by natural vegetation, and that very little urban land remains in its natural state. Land use was determined on a county basis, and is therefore relatively site-specific.

Exposure Assessment

As mentioned above, exposure assessment is limited to a determination of the overlap of physical disturbances with land. Areas of directly disturbed land are determined on the basis of a step function using average values reported in the literature for particular technologies and generating capacities. In this way, basic site requirements for power plants and mines are determined.

Risk Characterization

Two approaches are used. The first approach is quantitative and equates damage with land loss. The second is qualitative and attempts to interpret the effects of land loss on the affected species. Under this qualitative approach, species expected to occur in a particular land type are identified, and the habitat requirements for these species are outlined. Land use disturbance is interpreted in the context of loss of habitat requirements.

7.2.3.3 Operational Resource Requirements

The initial classification of land use is moderately labor- and cost-intensive. Determination of direct land loss requires minimal resources and expertise. Qualitative assessments of potential impacts to nonplant species requires personnel trained in wildlife biology.

7.2.3.4 Summary

This approach is unique among many of the assessment methodologies in that land loss and disturbance are endpoints of concern. The approach is limited to interpretation of effects associated with physical disturbances of land use; procedures for predicting and quantifying land use loss from chemical contamination have not yet been developed.

7.2.4 POTENTIAL IMPACTS TO ENDANGERED AND THREATENED SPECIES

7.2.4.1 Introduction

ANL documented the distribution of endangered and threatened species and their habitats in the Midwest and the reasons for the declining populations. The approach is not an ecological risk assessment in that no hazard, exposure, or risk assessments are conducted. The approach does, however, provide some useful concepts for receptor characterization; these are discussed below.

7.2.4.2 Description of Method

Receptor Characterization

ANL conducted an in-depth literature search and consulted state and Federal wildlife experts regarding the distribution of threatened and endangered species in the Midwest. Particular emphasis was placed on habitat characteristics and habitat requirements in the context of interpreting species decline. Such information is useful in predicting the potential response of a species to environmental changes.

The county-level distribution of designated species was determined. The resulting data base was designed for use as a screening mechanism to identify counties where potential conflicts may occur through the implementation of projected energy scenarios.

7.2.4.3 Operational Resource Requirements

This approach for receptor characterization is based on readily available information. The initial data collection and compilation is moderately resource-intensive and requires some expertise in the area of ecology. However, once the data are compiled, application of the approach should be inexpensive. Interpretation of potential impacts from environmental disturbances requires some understanding of ecology.

7.2.4.4 Summary

This approach is an easily-implemented, relatively low-cost, qualitative screening mechanism for evaluating the potential for damage to endangered and threatened species. It does not predict what effects, if any, will occur, but only estimates the potential for effects. Counties with more endangered species can be assumed to have a greater potential for detrimental effects.

No hazard, exposure, or risk components are incorporated into this approach; it is mainly applicable for receptor characterization and as a screening tool.

7.2.5 SPECIES DIVERSITY AS A TOOL IN ECOLOGICAL ASSESSMENTS

7.2.5.1 Introduction

ANL proposed a conceptual approach for incorporating ecosystem diversity measurements in ecological field assessments. Species diversity is an attribute of all ecosystems, and is often considered a primary indicator of ecosystem "health", stability, and resilience. Ecosystem resilience is a system's ability to recover without losing its intrinsic identity. The more resilient a system, the better that system is able to recover from environmental perturbations. Diversity indices can be used as a measure of ecosystem resilience. Several diversity indices were discussed.

The diversity approach is a tool for evaluating and monitoring the ecological environment. The approach provides unique concepts for receptor characterization, and can be used as a rough screening mechanism for estimating ecosystem vulnerability.

7.2.5.2 Description of Method

Receptor Characterization

The receptors under this approach are communities and ecosystems. Communities and ecosystems are defined both temporally and spatially, in addition to taxonomically. Abiotic and biotic characteristics of the system are defined and considered when determining diversity. Three types of diversity are defined: alpha diversity refers to species diversity at a particular site; beta diversity refers to species diversity among ecologically similar sites; and gamma diversity refers to species diversity among ecologically similar and variable sites. The approach results in a fairly complete characterization of communities and ecosystems.

7.2.5.3 Operational Resource Requirements

This approach to receptor characterization is resource- and data-intensive. Large amounts of data are needed on species composition, number, and distributions within and between systems. This requires extensive review of available data, and probably requires additional data gathering in the field. Experienced ecologists would be needed to collect and interpret the data.

7.2.5.4 Summary

This approach characterizes receptors at the community and ecosystem level. Abiotic and biotic as well as temporal and spatial aspects of systems are considered. The approach is not a risk assessment methodology; it is an environmental monitoring and evaluation technique. However, the diversity of a system can be used as a relative measure of the potential for damage following environmental disturbances. In this context, the approach is most appropriately used as a screening tool in ecological assessments. The approach, however, is relatively resource-intensive, and this may limit its usefulness.

7.3 COMPUTER SIMULATION MODELS FOR ASSESSMENT OF TOXIC SUBSTANCES (Eschenroeder et al. 1980)

7.3.1 Introduction

The computer simulation model described in this document is the result of an exploratory study, funded by the National Science Foundation, to develop a model to aid in the assessment of environmental effects of toxic substances. The model is a series of generalized differential equations based on bioenergetic parameters. The equations are used to calculate population biomass, expressed as biomass/energy equivalents, and concentrations of the chemical in each population. Lethal and sublethal effects of chemicals can also be incorporated into the model and the subsequent effects on biomass and chemical concentration in each population examined. A simplified example, DDT in a pond ecosystem, was described in the document. In the example, only aquatic organisms were modeled, and populations were grouped by trophic level.

7.3.2 Description of Method

Receptor Characterization

Although the model could be adapted to simulate many systems, it is applied in this document to a simple aquatic community. The community consists of one or two species at each trophic level. Populations of species at each trophic level are "lumped" and changes are simulated by each trophic level. Species that change trophic levels in their lifetimes (e.g., perch, which become pisciverous with age) are divided, based on biomass, into different trophic levels. Although temporal changes are not incorporated into this example, the possibility of incorporating it in future versions of the model is discussed.

Hazard Assessment

Damage functions, expressed in terms of dose, were constructed for rates of mortality, respiration, and feeding. The functions were constructed based on assumed baseline and saturation levels for the effect of concern, and a threshold concentration of contaminant eliciting the effect. Individuals were then assumed to be normally distributed with respect to the step-function.

Exposure Assessment

Exposure is calculated for each compartment, in this case, by trophic level. Chemical flux into the producer compartment is expressed as mass units of toxic material per kilocalorie of biomass/energy. Loss terms from the producer compartment include predation, mortality, and excretion. At higher trophic levels, exposure occurs only through the food chain. Thus, the chemical concentration in higher trophic levels is calculated as the influx by feeding minus loss terms including predation, mortality, and excretion. The incorporation of a bioconcentration factor from water into higher trophic levels was discussed as a possibility for future versions of the model.

Risk Characterization

The model uses two sets of differential equations to describe population dynamics and chemical concentration. In the example, the model was used to estimate change in biomass and chemical concentration in a simple aquatic system by trophic level. Toxic effects of chemicals are combined with exposure (i.e., dose) in the model by constructing injury functions. In this way, effects of chemical concentrations are fed back into the set of differential equations describing population dynamics. Risk is then expressed as the percent reduction in energy/biomass for each compartment. In the simplified version of the model, species were aggregated and competition was ignored, although with sufficient information, these two issues could be incorporated.

Predictions of residues were roughly validated using general information on DDT levels in different trophic levels of the environment compiled from the literature. The model was analyzed for sensitivity to effects at different trophic levels, and to variations in the damage functions. The model could be validated using a simple pond mesocosm or microcosm.

7.3.3 Operational Resource Requirements

The model requires some exposure-response data that are largely unavailable (e.g., for ingestion) for endpoints that might be difficult to measure for many systems, (e.g., biomass, respiration rates, feeding rates). It requires a high level of effort and skill, as well as a computer.

7.3.4 Summary

A major strength of the model is that it is very flexible. Although the compartments in the example were trophic levels, with sufficient information, compartments could be species or even age or weight class within species. Stochastic and temporal elements could also be incorporated. Sublethal effects such as feeding rate changes, as well as mortality, are included. Risk is presented as a reduction in biomass, which could easily be input to costing models. Because biomass and residue concentration were modeled on a time-specific basis, recovery dynamics of the system can be examined. A limitation of the model is that it uses bioenergetic terms and units that are unfamiliar to many people. Data needs are high, and with refinement of the model, data needs would be even greater. For this reason, the model is presently limited to very simple systems.

7.4 UNFINISHED BUSINESS: A COMPARATIVE ASSESSMENT OF ENVIRONMENTAL PROBLEMS. APPENDIX III, ECOLOGICAL RISK WORK GROUP (EPA/OPPE 1987)

7.4.1 Introduction

The objective of the Comparative Risk Project (CRP) was to estimate and rank current cancer risks, noncancer health risks, welfare effects, and ecological effects presented by 31 major environmental problem areas which EPA has some responsibility and authority to control; the purpose was to establish program and budget priorities. Separate workgroups were formed to evaluate each type of risk; this summary addresses only the ecological risks component evaluated by the Ecological Risk Work Group (ERWG), which was assisted by an expert panel convened by the Cornell Ecosystems Research Center.

The objective of the ERWG was to rank the relative ecological risks, under existing levels of control, posed by widely disparate categories of environmental problem areas including accidental oil spills, active hazardous waste sites, and depletion of the stratospheric ozone layer. Because of inconsistencies in the scope and scale of each problem area, types of potential and actual ecological damage caused by each problem area, and levels of data availability for each problem area, the ERWG recognized the need for a methodology that differed from a formal risk assessment procedure. Consequently, the ERWG used a semi-quantitative damage assessment procedure that relied in large part on the considered judgment of experts.

The procedure followed by the ERWG and the expert panel involved five major steps. First, the specific types of ecological stress agents associated with each environmental problem area were identified. Second, a set of terrestrial and aquatic ecosystem categories was defined. In the third step, the expert panel qualitatively evaluated the potential effects of each stress agent on the structure and function of each type of ecosystem, the reversibility of these impacts, and the time it would take for the ecosystem to recover after the stress agent was removed, and characterized the geographic scale of these effects. In the fourth step, papers were prepared for each problem area summarizing available information on sources and emissions, exposure, potential impacts on ecosystems, level of control, and quality of the available information. Finally, using these papers, each member of the ERWG subjectively prepared an aggregate ranking of each problem area (low, medium, or high) based on a separate ranking of effects on each ecosystem. The individual rankings were tabulated, and a final ranking was determined by consensus.

7.4.2 Description of Method

Receptor Characterization

The analysis focused on a generic set of 16 different freshwater, marine, estuarine, terrestrial, and wetland ecosystems. Analysis of hazard included consideration of impacts on community structure (e.g., alterations in trophic structure or species diversity), community function (e.g., alterations in primary production or rates of nutrient cycling), and particular species (e.g., endangered or economically important species). No specific temporal or niche characteristics were included routinely, although they may have been considered in some assessments.

Hazard Assessment

Hazard assessment focused mainly on a qualitative evaluation of the potential impacts resulting from each stress agent (not from problem areas directly). Stress agents included those transported through the atmosphere (e.g., gaseous phytotoxicants, acid deposition), those transported through surface water (e.g., pesticides, toxic inorganics, nutrients), those applied directly to terrestrial systems (e.g., pesticides, solid matter), and others (e.g., habitat alteration, ground-water contamination). Potential effects were estimated first with respect to the scale at which impacts would likely occur (e.g., local, regional, global). Next, the potential effects of each stress agent on each ecosystem were evaluated with respect to their potential intensity (high, medium, low, no effect), the nature of the effect (e.g., effects on ecosystem structure and function or on endangered or economically important species), the reversibility of the impacts, and the probable time scale for recovery following removal of the stress agent (years, decades, centuries, indefinite).

In most cases, the assessment was based on known effects on surrogate individual/population receptors rather than on direct ecosystem dose-response data. For some problem areas with a small number of stress agents (e.g., acid deposition), data on acute or chronic toxicity to individual species were used to evaluate hazard. However, most chemical stress agents considered were defined on the basis of chemical class (e.g., pesticides and herbicides, nutrients, toxic organics), so it is unclear whether toxicity was assessed on the basis of the most toxic constituent, the least toxic constituent, or some average toxicity value.

Certain modifying factors were considered for each stress agent. Several ecosystems (freshwater lakes, streams, and wetlands) were defined on the basis of whether or not they were buffered. Wetlands also were defined on the basis of whether or not they were isolated from other flowing surface water. Other modifying factors considered in evaluating hazard included water hardness (for inorganic chemicals) and bioaccumulation (for organic chemicals).

A qualitative assessment of the uncertainty associated with each stress agent/ecosystem hazard assessment was included. Situations in which the data and understanding were sufficient for certain or probable assessments were differentiated from those in which the stress-response relationship was poorly understood or adverse responses occurred infrequently. Qualitative assessments of the quality of data available also were included in each problem area summary paper.

In the final ranking scheme, the greatest weight was placed on the scale of impact of each problem area, followed by the reversibility of potential effects. However, no particular weighting criteria were presented. In particular, it is unclear how the aggregate rankings of each problem area were determined from the separate rankings of effects on each ecosystem.

Exposure Assessment

Exposure assessment was presented only in each problem area summary paper (exposure was not considered in evaluating impacts of stress agents on ecosystems) and included geographical extent, intensity, and frequency. All exposure pathways relevant to a particular problem area were considered. Exposure data consisted primarily of summary statistics on release quantities or proportion of a given ecosystem in which contaminant concentrations were in excess of applicable criteria. No attempt was made to provide concentration estimation methods. Data on toxicity modifying factors (e.g., water hardness, pH) were presented where available. Qualitative estimates of uncertainty were included.

Risk Characterization

The approach was highly qualitative and relied heavily on expert judgment. Maximum emphasis was placed on the integration of information on the hazards associated with multiple contaminants, multiple routes of exposure, and multiple stress agents associated with a particular problem area. Because it is highly qualitative, this approach can be broadly applied to a wide range of environmental problem areas.

Treatment of uncertainty was also highly qualitative, reflecting uncertainty in measurements as well as biotic and ecological impacts. No quantitative estimates (e.g., probability distributions, confidence intervals) were possible with this approach.

The approach could be validated internally by having a number of different work groups evaluate each problem area and compare their final relative rankings. External validation, calibration, or sensitivity evaluation would not be possible.

The approach as documented cannot be verified, because several critical steps cannot be reconstructed. Particularly absent are algorithms for aggregating component scores.

7.4.3 Operational Resource Requirements

For most problem areas, a limited amount of data (e.g., receptors, chemicals) are available. The approach allows comparison of problem areas with widely varied data bases. The cost and level of effort involved in using this approach are low relative to those associated with a similar effort based on quantitative risk assessments. However, proper use of this method requires the highest level of skill, experience, and ecological knowledge.

7.4.4 Summary

The Comparative Ecological Risk approach is not a formal risk assessment procedure aimed at quantifying ecological risks. Instead, it is a semi-quantitative damage assessment method aimed at ranking relative ecological risks posed by major environmental problem areas. Such a method is probably the only practical means for comparing the relative risks associated with widely disparate problem areas, particularly on a regional or national level. Its strengths lie in its ability to provide a broad integration of data on known exposures, potential hazards, and multiple pathways and stresses. For example, the problem areas receiving the highest risk ranking (stratospheric ozone depletion, CO_2 and global warming) were not those for which data were most available. The main limitations of this approach are its high reliance on qualitative judgments and the absence of repeatability due to a lack of sufficient documentation for some of the critical steps.